

Program Director, Regulatory CNS/Metabolism

Job ID: 00410681

Job Function

Clinical Regulatory Affairs

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

Regulatory Program Management 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. Like others in Regulatory Program Management, Program Directors are assigned their responsibilities by therapeutic area, and are assigned projects for different product development phases, as business needs dictate. Regulatory Program Management Program Directors provide regulatory leadership for one or more regional or global development projects. Regulatory Program Management Program Directors are responsible for the development and implementation of regulatory strategies to facilitate the development and approval of Roche medicines for human use. Program Directors are expected to lead more complex projects and represent PDR to cross-functional teams and groups with increased independence. Regulatory Program Management Program Directors are responsible for working cross-functionally and coordinating regulatory-related activities across PDR functions and with other internal partners. Regulatory Program Management Program Directors serve as the principal interface with primary reviewers from health authorities and for other interactions with

relevant regulatory-related external parties; managing the strategies for and execution of these interactions.

DUTIES & RESPONSIBILITIES:

- Continues to expand his/her knowledge base of laws, regulations and guidelines governing the development, licensure and marketing of drugs and biologics. Briefs teams and management, as appropriate
- Obtains and applies in-depth knowledge of Roche and regulatory guidelines, procedures and best practices
- Provides regulatory expertise and leadership to site, regional or global cross-functional teams and other groups
- Stays abreast of therapeutic area product development and other related business strategies and plans
- Serves as the primary PDR representative on one or more regional or global projects at any one point in time; typically complex projects
- Analyzes data, the regulatory environment and business objectives to recommend priorities
- Leads teams in developing, implementing and delivering the cross-functional regulatory strategy for each project or related assignment. Plays a lead role in helping ensure effective balance of time, cost, quality and risk so that regulatory strategies meet the needs of patients, prescribers, payers, regulators and Roche
- Plays a key role in assuring business objectives are understood and taken into account during regulatory strategy development
- Identifies and aligns cross-functional regulatory resources necessary to execute the regulatory strategy for each project or related assignment
- Works with others to ensure timely and appropriate cross-functional alignment and appointment to RAFT for each assigned project
- Presents and obtains approvals for the cross-functional regulatory strategy to various teams, committees and senior management
- Serves as the site, regional or global principal interface with primary reviewers from regulatory authorities or for other regulatory-related interactions with other external parties. Establishes effective working relationships with regulatory authorities and directs regulatory interactions for internal site, regional and/or global teams
- Provides internal teams with direction on regulatory authority interactions
- Manages ongoing RAFT meetings. Including providing ongoing leadership of regulatory deliverables and guidance on compliance, timing and other relevant matters. Manages RAFT resources
- Ensures cross-functional perspectives and expertise are incorporated into regulatory plans prior to decisions being made
- Manages decision-making and conflict resolution surrounding regulatory issues within cross-functional teams, including coordination between other business teams and RAFT team. Ensures appropriate escalation to team leaders or functional management, as necessary
- Oversees, coordinates and provides a first-line of internal approvals for regulatory submissions and other relevant regulatory documentation
- Responsible to ensure all PDR deliverables associated with each project or other assignment are completed within defined timelines and meet regulatory and other company guidelines
- Develops regulatory risk management and contingency plans. Communicates plans to management, as appropriate
- Works with other functions and functional management to ensure the relevant

regulatory team has appropriate budget and resources to meet objectives. Manages or co-manages relevant project budgets to ensure compliance with agreed parameters and provides routine and ad hoc budget reporting and other updates

- As relevant, provides day-to-day guidance and direction to less experienced Regulatory Program Management staff and their work supporting the same projects or other assignments
- Provides and receives direct and objective performance feedback on/from cross-functional team members
- As requested or otherwise appropriate, provides regulatory due diligence assessments in cooperation with other internal groups

Who You Are

QUALIFICATIONS & EXPERIENCE:

- Bachelors Degree required (life sciences disciplines strongly preferred)
- Advanced Degree in related field is preferred
- Average of 7 or more years' relevant experience in regulatory affairs or related functions in drug/biologics development/manufacturing
- Broad understanding of international regulations, processes and issues in drug/biologics development. Includes in-depth knowledge of GxP (Good Practices for quality guidelines and practices in the pharmaceutical/biotechnology or related industry), GCP (Good Clinical Practice), ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use), FDA, EMEA, NICE and other relevant guidelines
- In-depth experience working with the principles and techniques of data analysis, interpretation and clinical relevance (e.g., ISS, ISE, competitor data, etc.)
- Comprehensive understanding of product and safety profiles
- Familiar with competitive activity in the field
- Proven experience and effectiveness leading strategic regulatory activities for product development from entry into man through lifecycle management
- Experience participating in global product development teams
- Experience as a regulatory contributor for global original IND/NDA/MAA filings in the US or Europe is strongly preferred
- Previous people management (matrix management) experience
- International (2 or more markets) regulatory experience is a strong plus
- Strong computer skills, including Microsoft Office Suite (Word, PowerPoint and Excel) and Adobe Acrobat
- Fluent English and other language skills as needed
- As required, ability to travel

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