

## Regulatory Program Manager

Job ID: 00414376

**Job Function**

Regulatory Affairs

**Schedule**

Full-time

**Location**

United States-California  
South San Francisco

**Job type**

Regular Employee

**Company/Division**

Pharmaceutical

**Job Level**

Manager

### 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

#### GENERAL POSITION SUMMARY/PURPOSE:

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 Managers are assigned their responsibilities by therapeutic area, and are assigned projects for different product development phases, as business needs dictate. Regulatory Program Management Program Managers support regulatory program management for one or more development projects. Regulatory Program Management Program Managers participate in and support the development and implementation of regulatory strategies to facilitate the development and approval of Roche medicines for human use. Program Managers are expected to perform their responsibilities with supervision. Regulatory Program Management Program Managers work cross-functionally and help coordinate regulatory-related activities across PDR functions and with other internal partners.

## **JOB DESCRIPTION – PRIMARY DUTIES AND RESPONSIBILITIES:**

### **1. Intact & Cross-Functional Teams**

- Participates in site and/or regional and/or global PDR Program Management departmental meetings
- Participates as a standing member in the Regulatory Affairs Functional Team (RAFT) for assigned product development projects to help ensure effective and efficient cross-functional PDR coordination, appropriate resources, and timely, thorough and compliant execution
- As assigned or otherwise needed, assists relevant Regulatory Program Management Program Directors with their interactions, communications and planning with various other teams, dependent upon assigned projects and the associated development phase, such as early development core teams, global development teams and lifecycle teams. Helps Regulatory Program Management Program Directors coordinate cross-functional PDR contributions to product development projects and other related activities
- As assigned, may act as a standing or ad hoc member of other teams for special or ongoing initiatives and projects

### **2. Regulatory Program Management**

- 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 assigned therapeutic areas and projects. 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
- Stays abreast of therapeutic area product development and other related business strategies and plans
- Supports on one or more regional projects at any one point in time
- Analyzes data, the regulatory environment and business objectives to advise others on applicability of new or existing regulations and guidelines
- Participates in the development and implementation of the cross-functional regulatory strategy for each project or related assignment
- Supports Regulatory Program Management Program Directors in identifying and aligning cross-functional regulatory resources necessary to execute the regulatory strategy for each project or related assignment
- Supports Regulatory Program Management Program Directors and others in preparing and facilitating meetings, teleconferences and other interactions/communications with regulatory authorities. Establishes effective working relationships internally and externally with regulatory authorities
- Documents meetings, teleconferences and other interactions/communications with regulatory authorities
- Supports Regulatory Program Management Program Directors in providing internal teams with direction on regulatory authority interactions
- Participates in and supports management of ongoing RAFT meetings. Including providing ongoing guidance on regulatory deliverables, compliance, timing and other relevant matters. Helps manage RAFT resources, including documenting meeting minutes and conducting follow-up to ensure action items are completed in a timely and thorough manner

- Helps manage project plans and timelines for assigned projects
- As assigned, performs literature searches, prepares special reports and assembles documentation to support project teams
- Supports Regulatory Program Management Program Directors with a first-line of internal approvals for regulatory submissions and other relevant regulatory documentation. Helps ensure that all elements, quality, accuracy and format of regulatory submissions and other documentation comply with applicable laws, regulations and Roche standards
- Supports effective, best-practice maintenance of various clinical and non-clinical regulatory documents
- Helps Regulatory Program Management Program Directors manage all PDR deliverables associated with each project or other assignment to ensure these are completed within defined timelines and meet regulatory and other company guidelines
- Participates in and supports development of regulatory risk management and contingency plans. Develops associated communication plans for Regulatory Program Management Program Directors and their internal distribution
- Supports management of relevant project budgets to ensure compliance with agreed parameters and provides routine and ad hoc budget reporting and other updates
- As requested or otherwise appropriate, supports Regulatory Program Management Program Directors in providing regulatory due diligence assessments in cooperation with other internal groups

### **3. Other**

- Participates in and/or otherwise supports development and implementation of new or updated PDR and/or Regulatory Program Management-specific systems, processes, Standard/Department Operating Procedures (SOPs/DOPs) or other relevant tools
- Completes other routine and ad hoc analysis and reporting. Responsible to keep all internal customers, partners and stakeholders abreast of progress and interim updates. Does so by following prescribed departmental procedures, practices and protocols and by using standardized reporting and communications tools/templates and other resources
- Participates in other special projects, as and when assigned, or otherwise requested
- Participates in routine and ad hoc departmental meetings and other business reviews or meetings to remain, at all times, fully abreast and apprised of evolving internal and external needs and requirements. Expected to share best practices within the department and cross-functionally, identify and communicate opportunities for departmental enhancements and efficiencies
- Consistently complies with all governing laws, regulations, Roche SOPs and other guidelines

## **Who You Are**

### **SELECTION CRITERIA:**

Candidates for this position should hold the following qualifications, have the following experience, and be able to demonstrate the following abilities to be considered as a suitable applicant. Please note that except where specified as “preferred,” or as a “plus,” all points listed below are considered minimum requirements.

### **QUALIFICATIONS & EXPERIENCE:**

- Bachelors Degree required (life sciences disciplines strongly preferred)
- Advanced Degree in related field is preferred
- Average of 3 or more years’ relevant experience in regulatory affairs or related functions in drug/biologics

- development/manufacturing; • Demonstrated understanding of international regulations, processes and issues in drug/biologics development. Includes sound
- 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
- Demonstrated experience working with the principles and techniques of data analysis, interpretation and clinical relevance (e.g., ISS, ISE, competitor data, etc.)
- Demonstrated understanding of product and safety profiles; • Strong computer skills, including Microsoft Office Suite (Word, PowerPoint and Excel) and Adobe Acrobat
- Fluent English and other language skills as needed

#### **ABILITIES:**

- Has impeccable ethics. Demonstrates, or has proven abilities to demonstrate, Roche Values & Leadership Competencies;
- Outstanding attention-to-detail;
- Has working knowledge of the multidisciplinary functions involved in pharmaceutical/biotechnology product development, e.g., clinical development, clinical operations, biostatistics, commercial operations, etc
- Excellent project management skills: can prioritize multiple tasks and goals to ensure the timely, on-target and within-budget
- Good interpersonal, verbal communication and influencing skills: can influence without authority;
- Strong written communication skills;
- Good business presentation skills: is comfortable and effective when presenting to others, internally and externally;
- Good negotiation skills: knows how to complete deliverables by working effectively with others internally and externally
- Good judgment and decision-making skills: knows how to make trade-off decisions while balancing ethics and efficacy
- Works well within teams and is effective in collaborating with others internally and externally;
- Ability to travel (<10%)

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