

## **Associate Director, Technical Regulatory Team Program Management**

Job ID: 00412675

### **Job Function**

Technical Regulatory Affairs

### **Schedule**

Full-time

### **Location**

United States-California  
South San Francisco

### **Job type**

Regular Employee

### **Company/Division**

Pharmaceutical

### **Job Level**

Executive (Director/VP/SVP)

## **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**

### **Level : Associate Director**

Technical Regulatory is a global function that supports strategic regulatory and submission activities for the Roche and Genentech product portfolio. Support of individual portfolio projects is managed through a Technical Regulatory Team, led by a Technical Regulatory Lead (TRL) who matrixes with other key development and commercial teams to ensure cross-functional alignment of strategy and execution.

An Associate Director level position is available for an individual to lead a TRT Program Management function that supports the Biologics Platform portfolio. Reporting to the Global Head of Technical Regulatory – Biologics, this individual will work with the Biologics Platform Leadership Team to establish expectations and competencies for TRTs and Technical Regulatory Leads (TRL) at all stages of development/commercialization. The TRT Program Management function will be responsible for TRL development and TRT training programs with support of project management resources and manage TRL talent development

processes. In addition, the Associate Director of TRT Program Management will serve as an advisor to TRLs on matters of TRT project management expectations and logistics including those related to Health Authority and Affiliate interactions and planning, coordination and strategy of global filing and regional execution activities. This individual may also manage a small project management group to assist TRLs in project management and training on relevant PM. tools

At the portfolio level, The TRT Program Management function will create and manage processes related to regulatory strategy review and governance including ensuring teams create and maintain a Technical Regulatory Strategy Document and that processes for cross-functional communication of technical regulatory risk are in place. This individual will be the primary contact to leaders in key stakeholder organizations regarding TRT and TRL interactions, roles and responsibilities and deliverables and will coordinate joint meetings between regulatory (BioRAC) and stakeholder advisory/governance bodies (BQC, LSTDC, etc) when needed. This individual will be responsible to plan and manage an annual portfolio review of technical regulatory programs, and assist the Biologics Platform Leadership team in linking resource planning to strategic Portfolio management.

## **Who You Are**

MS or Ph.D. in a technical field with 10 years in the biotech industry, including 5+ years proven experience leading and or managing teams in a matrix environment. Strong project management and communication skills, as well as evidence of effective skills in people and team development. Well versed in technical lifecycle of biologic products, and familiarity with technical regulatory requirements and planning of regulatory strategy.

Genentech is an Equal Opportunity Employer.