

## **Associate Program Director, Regulatory Small Molecule Development**

Job ID: 00413962

### **Job Function**

Technical 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**

As a product manager, you will be responsible for supporting the preparation, assembly, and review of both product and facility-related Chemistry Manufacturing and Controls (CMC) regulatory submissions.

The successful candidate must have broad regulatory and technical knowledge applied to develop, execute and provide oversight in the execution of complex regulatory initiatives and strategies.

The successful applicant will be required to apply practical scientific understanding of drug substance manufacturing facilities and knowledge of pharmaceutical manufacturing to facilitate the preparation and review of regulatory submissions and ensure compliance with applicable regulations and guidelines. The individual will lead and/or participate in cross-functional project teams and work effectively with multiple disciplines and personalities. The candidate will support ex-US filings, as appropriate and as requested by corporate partners. Additional responsibilities may include leading or participating in departmental operational

excellence and business process initiatives.

Self-supervisory with senior management guidance on strategy. Exercises considerable latitude in determining objectives and approaches to assignments.

The Regulatory Manager must maintain a high level of professionalism, efficiency, and commitment. The successful candidate will demonstrate effective problem solving, strong understanding of regulatory affairs, excellent interpersonal skills and the ability to prioritize multiple tasks. Must have a proven ability to communicate effectively in both a written and verbal format. Ability to work both independently or collaboratively in a team structure. The incumbent will be interacting with FDA to facilitate timely review and approval of submissions.

## **Who You Are**

The candidate must possess a Bachelor's degree in sciences (PhD preferred) with a minimum of 8-12 years industry experience in regulatory, manufacturing, or quality. The position requires a candidate with strong written, interpersonal and communication skills, including giving effective presentations. In addition the candidate must have demonstrated the ability to coordinate and work effectively with cross-functional teams and drive results. Knowledge of FDA regulations, ICH guidelines are desirable. Scientific writing and editing skills are a plus. The candidate may be required to travel to other Roche sites occasionally. Genentech/Roche is dedicated to fostering an environment that is inclusive and encourages diversity of thought, style, skills and perspective.

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