

Sr Regulatory Product Manager/Scientist

Job ID: 00410814

Job Function

Commercial 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

In the position of Senior Regulatory Product Manager in Technical Regulatory Affairs, you will be accountable for the preparation of regulatory submissions and strategies supporting the product's lifecycle and business needs. This role within Pharma Technical Regulatory is focused on the development of strategies supporting biologic marketed products. The successful candidate must have demonstrated leadership capabilities, a proven ability to work cross-functionally, and recognized strengths in collaboration, teamwork and communication. He/She will be tasked to navigate and lead the preparation of complex global regulatory strategies with support from global team members representing both technical regulatory and various cross-functional representatives. The successful candidate must have an ability to develop and drive innovative solutions to complex regulatory strategies while maintaining compliance with regulations. With a focus on biologics marketed products, he/she will also be required to provide regulatory support for relevant quality systems such as change control, discrepancy management, and inspection management. Additionally, he/she will support departmental business processes to document and improve best practices and work efficiencies.

He/she will be responsible for leading a team that delivers timely compilation and of all necessary documentation for regulatory submissions to support technical content of regulatory submissions. He/she will ensure quality; content and format of regulatory submissions comply with applicable regulations and guidelines governing the development,

licensure and marketing of drugs and/or biologics.

The Regulatory Senior Manager must maintain a high level of professionalism, efficiency, and follow-through as the primary regulatory liaison for the assigned site/product. The successful candidate will demonstrate effective problem solving, strong understanding of CMC regulatory, excellent interpersonal/collaboration skills and the ability to prioritize multiple tasks. Must have a proven ability to communicate effectively in both a written and verbal format. Have a demonstrated ability to work both independently or collaboratively in a team structure, including a proven ability to work well under pressure. The incumbent will be skilled to lead communications with FDA and other regulatory agencies to facilitate review and approval of submissions.

Who You Are

The candidate must possess a Bachelor's degree in sciences with a minimum of 10-12 years industry experience in regulatory, manufacturing, or quality related field in the pharmaceutical/biotechnology Industry. The position requires a candidate with strong written, interpersonal/collaboration 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 required. Scientific writing and editing skills are a plus. The ideal candidate will have strong experience in Regulatory CMC, as well as, biologics manufacturing or quality assurance experience. He/she must be detail oriented with strong leadership skills and excellent interpersonal, collaboration and communication skills. The candidate will be required to travel to other Roche sites on a periodic basis approximately once every 3-6 months. Genentech/Roche is dedicated to fostering an environment that is inclusive and encourages diversity of thought, style, skills and perspective. Genentech/Roche is an Equal Opportunity Employer.

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