

Regulatory Advisor, CMC Small Molecule, Marketed Products

Job ID: 00404646

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

The Regulatory Advisor will be responsible for developing global regulatory strategy, writing high quality dossier and leading teams for assigned projects to obtain timely approvals of Roche applications. The Roche Pharma Technical Regulatory leadership team is composed of seasoned technical experts whose focus is to collaborate with Roche Scientists and International Health Authorities to drive development of innovative regulatory policy, and ensure the approval of Roche products developed using novel and efficient process development strategies. This position will require regular interaction with management from multiple internal functional areas, corporate partners, international regulators and external experts.

The individual will lead and/or participate in cross-functional project teams and work effectively with multiple disciplines and personalities. The candidate will support both US ex-US filings, as appropriate and as requested by corporate partners. Additional responsibilities will include leading departmental operational excellence and business process initiatives, as well as, proactively communicate with Regulatory and cross functional personnel and partners in support of internal and partner associated goals.

The Regulatory Advisor 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. Have a proven ability to work well under pressure. The incumbent will be skilled to lead communications with FDA and regulatory agencies to facilitate review and approval of submissions.

Who You Are

The candidate must possess an advance degree in sciences (PhD preferred) with 12 years or more of experience in pharmaceutical industry. The ideal candidate will have strong experience in Regulatory CMC, as well as, pharmaceutical development experience. He/she must be detail oriented with strong leadership skills and excellent interpersonal and communication skills. 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. Genentech/Roche is an Equal Opportunity Employer

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