

CMC Regulatory Product Manager - Biologics

Job ID: 00407156

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

There is an opportunity in the Technical Regulatory organization at Genentech at the Product Manager level. This position requires use of regulatory and technical knowledge to develop, execute and oversee regulatory initiatives and strategies. This individual will work with cross-functional project teams to develop regulatory strategy and ensure the success of regulatory filings through submission of high quality documents supporting the company's development product portfolio. Responsibilities will include accountability for IND, IMPD, and BLA/NDA/MAA applications as well as informational and pre-submission meetings with global health authorities, partners, and industry experts. Additional responsibilities include leading departmental business process initiatives, and proactive communication with Regulatory and cross-function personnel and partners. Candidates with a combination of broad technical, process and product development, and CMC regulatory experience are desired.

Who You Are

The candidate must possess an advanced degree in a field relevant to biopharmaceutical CMC, such as Chemical Engineering, Biochemistry, Microbiology, Analytical Chemistry, or Molecular Biology. A minimum of 5 years' experience in the biopharmaceutical industry is preferred. The candidate must have significant experience dealing with issues related to

CMC regulatory requirements and must have leadership skills and excellent interpersonal and communication skills.

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