

Associate Scientist-Clinical Pharmacology (Biologics)

Job ID: 00410703

Job Function

Early Development/ Translational Medicin

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 Clinical Pharmacology Department at Genentech, Inc. is seeking a Ph.D. level Associate Scientist or Scientist who is driven to understand the clinical pharmacokinetics and pharmacodynamics of novel drug candidates in the area of Biologics. This individual will be primarily responsible for the clinical pharmacology activities of Biologics in clinical development. This person will have responsibility for the Clinical Pharmacology strategy in order to ensure that appropriate dose/route/schedule decisions are made using the state of the art modeling and simulation strategies that are aligned with project needs. This will be accomplished by working in close partnership with Clinicians, Biostatisticians, Clinicians and project teams. Responsibilities will include planning and reviewing study designs, analysis plans, data analysis, interpretation of PK/PD as well as planning, implementation and organization of regulatory filings (worldwide) and presentation of data at cross-functional teams, department meetings, conferences and regulatory meetings (worldwide). Additionally this individual will also be directly involved in leading project sub-teams and representing the function at cross-functional project teams.

Who You Are

- Relevant experience and demonstrated impact on drug development is expected and experience with Biologics is highly desired. In addition, experience in the preparation of regulatory interactions and good knowledge of GCP and regulatory guidelines is

highly desirable. Leadership abilities are a plus.

- The candidate must have excellent communication skills, the ability to work independently and the ability to work effectively on interdepartmental project teams. Familiarity with quantitative approaches in drug development, working knowledge of modeling software (NONMEM, ADAPT II and WinNonlin) and the ability to plan, organize, and critically assess and/or perform PK/PD data analyses are essential
- A Ph.D. or equivalent in Pharmacokinetics, Pharmaceutical Sciences, Biomedical Engineering or related discipline with minimum of 5 years of industry Clinical Pharmacology experience are required (Sr. Scientist requires significantly more experience).

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