

Senior Bioassay Scientist, Global Quality Organization

Job ID: 00394467

Job Function

Quality

Schedule

Full-time

LocationUnited 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

Dept: Biological Assays, Method Management and Technology, PTQBP

Job Category: Quality

Location: SSF

Department: MMTech (Method Management and Technology)

Description: Senior Scientist Bioassay

Summary

The Biological Assay Function within Genentech's Global Quality Organization is responsible for life-cycle management and innovation of post-BLA biological potency methods and specifications. We serve as the scientific and technical Center of Excellence for biological assays and analytical ELISAs within Commercial Quality for the Roche/Genentech Global Quality Network. We are looking for an experienced Senior Scientist to take on a leadership role and to play an integral part in the function.

Requirements

Candidates must have in-depth experience in the development of cell-based potency assays and immunoassays in an industrial setting. Understanding of mechanism-of-action of antibody-based protein therapeutics is essential. Broad experience with a variety of biological in-vitro systems is required. Familiarity with antibody effector function determination and enzymatic assays would be an asset. Prior experience in assay validation/qualification and technology transfer are highly desirable, as is GMP experience and a strong sense for compliance. Familiarity with common applications analyzing the dose-response relationship will be very helpful (SoftMaxPro, XLFit, PLA etc). Working knowledge of statistical approaches will be helpful. Must be highly motivated and comfortable working independently in a fast-paced environment. Experience with regulatory submissions (IND/BLA) and Health Authority interactions will be advantageous. Management experience of direct reports is expected.

Who You Are

Education and Experience

The successful candidate must have a Ph.D. in Biological Sciences (Immunology, Cell Biology or related field) and significant knowledge of the biological assay field for CMC and Quality applications. Prior experience in performing quantitative cell-based and biochemical/immunological assays in the context of relative potency determination is required. Successful candidates will be expected to be flexible, strategic as well as hands-on, able to design well-defined experiments as well as development and validation strategies, analyze and present data, write protocols and reports, justify changes to existing methodology, and to support global regulatory filings and responses with scientific and technical expertise. Excellent skills in teamwork and collaboration with international partner organizations are required.

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