

QC Sr Scientist - Commercial

Job ID: 00411693

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**Position Summary:**

The Commercial Control System Lifecycle Management function of MMTech at Genentech has an open position for a QC Scientist/Senior QC Scientist to support lifecycle management of commercial biologics control systems. This position is part of a function responsible for developing and implementing strategies to systematically evaluate and update control systems for the Genentech/Roche product portfolio.

MMTech is part of the Genentech/Roche commercial quality organization and is responsible for method validation, control systems and specifications, reference standards, assay transfers, and providing scientific/technical support for the global QC Network across the commercial biotechnology product portfolio.

Job Description:

The individual will support the development, implementation, and maintenance of strategies to systematically assess and update commercial product control systems. He/she will manage product, process, and external knowledge to ensure that control systems reflect current product and process understanding, analytical technologies, and Health Authority

expectations. The individual will be responsible for contributing to reports that document information supporting control system assessments and revisions.

As part of the control system evaluation and revision, this individual will:

- Oversee comprehensive control system assessments based on: identification of critical quality attributes, method and process capabilities, current industry practices, and contemporary Health Authority expectations
- Lead cross functional technical teams that perform detailed physicochemical characterization, method development/validation, and sample testing so that control system revisions are effectively managed and aligned with present-day requirements
- Provide scientific input and technical oversight to support control system changes
- Partner with subject matter experts to identify and complete key activities required for control system updates
- Collect and analyze results from product release and stability testing for use in evaluating and updating specification acceptance criteria
- Provide technical review and approval of analytical control system cGMP documents
- Support and coordinate quality assurance activities/reviews in Quality systems (e.g. Change Control, Discrepancy Management, etc.) to ensure compliance to procedures, current GMPs, and regulatory requirements
- Support regulatory submissions and inspections through authorship of relevant CMC sections, written responses to agency requests, and direct interactions with Health Authorities

Applicants should be comfortable working both independently and collaboratively as part of a team. The position offers opportunities for professional and scientific growth in a dynamic work environment.

Who You Are

- Candidates must have a Ph.D. in Biological Sciences, Analytical Chemistry or related field, a minimum of 8 years of biopharmaceutical industry experience, and strong background in one or more of the following areas: quality, analytical sciences, process development, manufacturing, or pharmaceutical development
- Demonstrated team leadership and collaboration skills with ability to resolve conflicts and negotiate agreements through influencing and diplomacy
- Proven ability to critically evaluate scientific and technical information to devise strategies to solve complex problems
- Knowledge of and experience with cGMP, compliance, and regulatory requirements for biopharmaceuticals
- Experience with Labware LIMS, Trackwise, EDMS, Change Control and other quality systems is a plus
- Prior experience in analytical control strategy development and implementation for biological products is preferred
- Background in analytical chemistry across a wide range of technologies (HPLC, CE,

MS, etc.) is desirable

- Knowledge of recombinant protein posttranslational modifications, experience in biotechnology product characterization, and understanding of protein structure and function relationships is preferred
- Experience in authoring CMC sections, responding to Health Authority questions and direct interactions is highly desired
- Excellent planning and prioritization skills with the ability to multitask and adapt to change
- Strong written and verbal communication skills with proven record in report writing
- Highly motivated and self-driven individual with the ability to work with minimal supervision to schedule, track, review, and report progress

Genentech is an Equal Opportunity Employer.