

## Sr Qc Assoc

Job ID: 00411690

### Job Function

Quality

### 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

Job Duties/Responsibilities:

- Perform microbiological, biochemical and analytical lot testing of raw materials, E. coli and mammalian cell banks, commercial and clinical fermentation, purification, and final product samples according to GMPs.
- Review data and assess against established acceptance criteria.
- Evaluate data to identify trends and/or establish limits.
- Identify gaps in and potential improvements to systems and procedures.
- Perform equipment qualification and or maintenance.
- Prepare and maintain standards, controls, stocks, and cultures per established procedures.
- Assure and apply GMP throughout all operations.
- Coordinate with customers to support multi-site operational activities.
- Present analytical procedures and results during internal and external audits and regulatory inspections.
- Participate in and/or lead projects and process improvements.
- Perform other duties as requested by managers to support Quality activities.
- Works to meet schedules, timelines and deadlines.

- Meets scheduled performance of 95% on time.

## Technical Duties/Responsibilities

- Write technical protocols and reports under limited supervision.
- Identify and propose resolutions for study or project deviations.
- Provide input to and participate in assay transfer and assay validation.
- Perform technical review of data derived from complex tests.
- With limited supervision, design and execute quality investigations and CAPA (corrective actions preventive actions) initiatives as needed.
- Identify, troubleshoot, and propose resolution to technical problems.
- Identify and propose resolution for discrepancies.

## Who You Are

### Requirements

- B.S./B.A./M.S./M.A. degree in Microbiology or related field and seven or more years experience in the pharmaceutical or biopharmaceutical industry or an equivalent combination of education and experience.
- Experience in the conduction of microbiological assays such as bioburden, PCR, LAL and Sterility testing.
- Demonstrated ability to apply knowledge of scientific theories, principles, and techniques used in analytical or biological test procedures.
- Consistently and independently exercises sound judgment, reasoning and problem solving.
- Capable of working under minimal supervision and determining own short term priorities.
- Strong verbal and written communication skills, ability to organize and present information both formally and informally.
- Demonstrated proficiency in technical writing.
- Ability to work off-shift, weekends and holidays as needed.
- Must be physically able to perform the following tasks: Work in a laboratory environment including biosafety cabinets and isolator half-suits.
- Able to lift up to 25lbs. Sit, stand and move within work space for extended periods. Work with bacterial and fungal cultures.

Genentech is an Equal Opportunity Employer.