

Qc Assoc II

Job ID: 00411665

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

E2/E3 position depending on experience of candidate.

Perform microbiological testing of raw materials, E. coli and mammalian cell banks, commercial and clinical fermentation, purification, and final product samples to meet standard lead times. Review data and assess against established acceptance criteria. Identify discrepancies, participate in quality investigations and CAPA initiatives as needed. Participate in assay, facility, equipment and process validation. Perform equipment qualification and maintenance activities. Support nonroutine microbiological projects and studies. Prepare and maintain standards, controls and stock cultures per established protocols. Support the maintenance and compliance of operational areas. Assure strict adherence to cGMPs throughout operation. Ensure training qualifications are up to date. Identify and support resolution of technical problems. Actively participate in group projects and process improvements. Perform routine maintenance duties to ensure inspection ready state. Draft protocols and reports under supervision. Work with internal and external groups

to develop methods for clinical products for in process and final products testing.

Who You Are

Requirements:

Experience conducting microbiological testing utilizing the following methods: Bioburden, PCR, LAL and Sterility testing. Ability to communicate clearly and professionally, written and verbally. Strong grasp of scientific theories, principles and techniques used in biological or analytical test procedures. Has strong technical writing skills. Ability to exercise sound judgment, reasoning and problem solving. Have the ability to independently design, execute projects and interpret results. Sound knowledge of cGMPs and regulations. Ability to work off-shift, weekends and holidays as needed. Experience using computer software (Word, Excel, and PowerPoint). Proficient in the use of SAP and Labware LIMS. 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.

Education:

BS degree in Microbiology or related field.

Minimum 4 years of microbiological pharmaceutical experience.

Genentech is an Equal Opportunity Employer.