

## QC Scientist - IMP Quality Operations

Job ID: 00413516

### Job Function

Quality Control

### 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

### Responsibilities

- Perform technical and compliance review of analytical testing results for bulk, final product, pre-clinical, cell banking and stability products
- Compile analytical data for bulk, final product, pre-clinical, cell banking and stability products
- Set up stability studies for clinical products in accordance internal PQS and ICH stability guidelines.
- Plan and prioritize new stability studies to ensure regulatory submission timelines are met.
- Review and approve time point data to ensure regulatory compliance.
- Manage inventory of all stability studies, including sample submission to partner labs and cycle counting
- Assess and approve discrepancies of clinical and pre-clinical products
- Technical proficiency in analytical methodology and adherence to cGMP compliance
- Train colleagues on stability, assay review and analytical methodology as appropriate
- Identify and address gaps in systems and procedures for continuous improvements.
- Accomplish corporate, operational and departmental goals
- Exert influence in the development of objectives and long range goals of the organization
- Make independent decisions around complex issues in alignment with Roche policies
- Support internal and external audits

- Work with internal departments and outside vendors, collaborators and partners concerning projects and commitments
- Mentor and supervise (as required) other staff members on QC related, processes and projects.

## **Who You Are**

Job Requirements;

- BA/BS degree in life science, or equivalent and at least ten years of relevant experience in quality control, quality assurance or equivalent experience in the pharmaceutical/biotechnology industry.
- Excellent knowledge of cGMPs or equivalent regulations and ability to interpret and relate Quality standards for implementation and review.
- Experience working with Labware LIMS, SAP and Trackwise are preferred
- Knowledge of regulatory requirements and industry expectations for analytical testing and stability.
- Ability to interpret and relate Quality standards for implementation and review, and apply Quality, compliance, and risk concepts to make sound technical decisions.
- Ability to communicate clearly and professionally both in writing and verbally.

Genentech is an Equal Opportunity Employer.