

## QA Specialist I-Swing

Job ID: 00414339

### Job Function

Quality

### Schedule

Full-time

### Location

United States-Oregon  
Hillsboro

### 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

**Main Purpose of the Position:** Provide direct manufacturing Quality Assurance support to Production (Inspection, Packaging, Aseptic Operations) in a GMP environment. Act as a key Quality contact to manufacturing for discrepancy management, batch review, and line support. Assure compliance with cGMP regulations, Roche / Genentech standards, and applicable Regulatory Guidelines. Solve routine Quality Assurance issues limited in scope and complexity following cGMP regulations and Genentech standards. Perform assigned tasks and work to achieve company goals and department objectives. Job Duties/Responsibilities: Follow company policies and procedures. Maintain a state of inspection readiness. Provide input to the development of personal performance goals and departmental objectives. Meet assigned targets and timelines with minimal supervision. Prioritize assigned tasks within a fast paced environment. Participate in process improvement and system design teams. Provide assistance to customers in support of departmental functions. Work with colleagues to maintain cross-functional and cross-site process and procedural consistency. Receive specific instruction and work independently to complete tasks. Apply basic theory and technical principles to address routine problems. Troubleshoot and assist in the resolution of Quality issues by fostering effective interdepartmental and cross-functional partnerships. Sign documents for activities as MQA as described by Genentech policies, procedures and job descriptions. Be accountable for behaviors as described in Genentech's Core, Common, and Critical Competencies. Perform any other tasks as requested by Management to support Quality oversight activities. Technical Duties/Responsibilities: Perform Inspection and Packaging AQLs. Perform Line

Clearances for Inspection, Packaging, and Aseptic Operations areas. Initiate and close discrepancies and child records as required. Review batch records in the Inspection, Packaging, Aseptic Operations areas. Perform Assessor and Evaluation activities in the Discrepancy Management System. Interact with interdepartmental contacts on discrepancy assessment and resolution. Provide Quality oversight to internal and external customers. Review and approve controlled documents relating to processes, equipment, facilities and utilities in the manufacture of product. Collaborate with departments to ensure that all review activities are executed efficiently and effectively. Support Quality process improvement initiatives. Support the execution of departmental deliverables assigned by project teams. This is a SWING shift position: Monday, Tuesday, Wednesday, Thursday, and Friday – 4:30pm to 1:30am

### **Who You Are**

B.A. or B.S. degree (preferably in Life Science) and 0-2 two years experience in the pharmaceutical, biopharmaceutical or related industry, or an equivalent combination of education and experience Knowledge of cGMPs or equivalent regulations strongly preferred Ability to interpret Quality standards for implementation Ability to independently evaluate situations and propose potential solutions Ability to interpret Quality standards for implementation Ability to communicate clearly and professionally both in writing and verbally Flexibility in problem solving and work hours to meet business objectives

Genentech is an Equal Opportunity Employer.