

## Quality Principle I

Job ID: 00408794

### 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

### Description Main Purpose of the Position:

- Direct Quality support staff and operations in accordance with cGMP regulations and Roche standards.
- Provide leadership and guidance to immediate staff hosting inspections or performing Quality Systems functions as assigned.
- Provide the Director, GQIM, with expertise in device and/or combination product inspection issues and risks.

### Job Duties/Responsibilities:

- Optimize resources with the PTQS department.
- Interpret, execute and recommend improvements to Quality operational policies, plans and procedures.
- Provide input to department budget.
- Monitor and control expenditures against the department budget.
- Provide input for the development of overall Quality objectives and long-range goals.
- Notify Senior Management of potential quality or regulatory issues that may affect product quality or regulatory compliance.

- Lead and participate in continuous improvement initiatives for Roche Quality Systems.
- Sign documents for activities as authorized and described by Genentech policies, procedures and job descriptions.
- Be accountable for behaviors described in Core, Common and Critical Competencies.
- Perform any other tasks as requested by Senior Management to support Quality oversight activities. Technical

#### **Duties/Responsibilities:**

- Develop and oversee implementation of the Inspection Risk and Readiness systems to ensure on-going inspection readiness.
- Collaborate with Pharma Technical Operations and Quality areas as needed to identify inspection risks and mitigation plans.
- Serve as a GQIM primary point of contact and liaison for assigned sites
- Manage and oversee the inspection readiness program across sites to ensure proper deployment and reporting of inspection risks
- Lead or support regulatory inspections as appropriate.
- Collaborate with sites to develop and communicate inspection strategy, approach and goals.
- Communicate potential inspection risks and current state of inspection readiness to Senior Management.
- Provide input into the design and presentation of inspection readiness performance metrics
- Act as an advisor to internal project teams by providing extensive knowledge of regulatory requirements, industry standards, and company strategy.
- Attend and participate in external regulatory and/or compliance organizations, and applicable industry conferences to exchange information regarding current regulatory inspections and to stay current on inspection trends.

#### **Who You Are**

Qualifications: Education, Experience, Knowledge and Skills: (Minimum requirements)

- B.S. or B.A. degree (preferably in Life Science) and at least twelve years relevant experience in the Pharmaceutical or biopharmaceutical industry
- Sound knowledge of cGMPs or equivalent regulations
- Demonstrated knowledge and execution of Quality operations and processes
- Background in device or combination product manufacturing and quality aspects
- Ability to interpret and relate Quality standards for implementation and review
- Ability to communicate clearly and professionally both in writing and verbally
- Flexibility in problem solving, providing direction and work hours to meet business objectives

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