

## Senior Supervisor, Change Control

Job ID: 00414451

### Job Function

Management Quality

### Schedule

Full-time

### Location

United States-California  
South San Francisco

### Job type

Regular Employee

### Company/Division

Pharmaceutical

### Job Level

Team Leader

## 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:

- Supervise and develop staff completing Change Control activities and drive resolution of complex change control issues following cGMP regulations and Genentech standards.
- Supervise performance and development of direct reports to ensure achievement of organizational and department goals and a productive environment.

### Job Duties/Responsibilities:

- Manage and administer all aspects of people processes related to the employee lifecycle. This includes the selection, hiring and training of personnel on company and department policies, systems and processes. Manage and communicate compensation related information per company guidelines.
- Coach and develop staff by providing an environment that encourages ongoing personal and professional development. Manage and ensure the setting of realistic personal goals for staff and provide regularly scheduled feedback throughout the year. Ensure staff receives appropriate knowledge and skill development and growth opportunities.
- Determine and communicate objectives and accountabilities for direct reports.
- Regularly review staff progress in meeting objectives.
- Recommend improvements to Quality operational policies, plans and procedures.
- Ensure activities are completed on time and issues resolved within budget.
- Make recommendations to department budget and staffing needs.

- Notify Senior Management of potential quality or regulatory issues that may affect product quality or regulatory compliance.
- Participate in continuous improvement initiatives for Genentech Quality Systems.
- Sign documents for activities as authorized and described by Genentech policies, procedures and job descriptions.
- Be accountable for behaviors described in Genentech's Core, Common and Critical Competencies.
- Perform any other tasks as requested by Senior Management to support Quality oversight activities.

#### Technical Duties/Responsibilities:

- Oversee the impact assessment of proposed changes and ensure appropriate approvers are selected for changes.
- Supervise change control activities for validated systems, qualified equipment, and controlled documents.
- Participate in cross-site change management forums.
- Supervise staff conducting change control activities for quality and business systems support in GMP areas.
- Participate in business process improvement programs and process redesign initiatives.
- Promote and provide guidance in Good Documentation Practices.
- Supervise lot release restrictions imposed by system, process, method and equipment changes.
- Ensure the completion of required actions prior to lifting lot release restrictions.
- Assist in developing training content and qualifications for change control processes and change management applications.
- Act as a resource for Change Control knowledge management within Quality Operations and across site Quality departments.
- Collaborate with site Quality and Production units in the administration, access, and communication of the Change Control system.
- Participate in change control automation and business process improvement initiatives.
- Supervise Record Management, Retention and Repository program activities and processes.
- Collaborate with Quality and Production departments to maintain GMP records.
- Ensure backup and disaster recovery system activities are implemented and maintained for critical GMP records.
- Ensure data integrity and recoverability of electronic GMP records according to Genentech policy.

## Who You Are

- B.A. or B.S. degree (preferably in Science or Engineering) and five years relevant experience in the pharmaceutical or biopharmaceutical industry, including two or more years of supervisory experience, or an equivalent combination of education and experience
- Sound knowledge of cGMPs and Change Control guidelines set forth in ICH Q10
- Ability to interpret and relate Quality standards for implementation and review
- Ability to make sound decisions about scheduling, allocation of resources, and managing priorities
- Ability to communicate clearly and professionally both in writing and verbally
- Flexibility in problem solving, providing direction and work hours to meet business

objectives

Genentech is an Equal Opportunity Employer.