

**Sr. Technical Mgr. (Quality Change Control, Change Controller)**

Job ID: 00414710

**Job Function**

Quality Assurance

**Schedule**

Full-time

**Location**United States-Oregon  
Hillsboro**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: Solve a wide range of challenging issues that impact multiple functions by managing change records in accordance to cGMP regulations and Genentech standards. Manage staff performing a variety of routine and complex change control activities to meet cGMP regulations and Genentech standards. Perform assigned tasks and manage performance and development of direct reports to ensure achievement of organizational and department goals objectives. Job Duties/Responsibilities: Manage and administer all aspects of people processes related to the employee life cycle. 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 goals for staff and provide regularly scheduled feedback throughout the year. Ensure staff receives appropriate knowledge and skill development and growth opportunities. Set operational objectives for staff. Follow company policies and procedures. Help maintain a state of inspection readiness. Lead and participate in improvements to Quality operational policies, plans and procedures. Manage routine department activities and complex Quality initiatives. Ensure completion of activities and initiatives on time and within budget. Serve as the Quality representative on cross-functional and multi-site teams. Identify, design, and implement process and system improvements. Lead and participate in the design and implementation of department and cross-functional initiatives. Apply advanced theory, technical principles, and expert judgment to address a broad range of difficult problems. Troubleshoot and direct the

resolution of Quality issues by fostering effective interdepartmental and cross-functional partnerships. Serve as a technical subject matter expert (SME) in support of department functions. Train personnel on relevant business processes. Be accountable for behaviors as described in Roche's Core Competencies. Technical Duties/Responsibilities: Function as a Change Controller by assessing, reviewing, approving and closing change records. Ensure the management of lot release restrictions imposed by system, process, method and equipment changes. Author, edit, word process, and release controlled documents relating to Quality Systems. Provide training to new employees and internal customers on policies and procedures for the Change and Document Control systems. Facilitate and contribute to cross-functional change management forums. Recommend change control strategies that have minimal impact of validated systems and qualified equipment. Lead business process improvement and process redesign initiatives. Collaborate with departments to ensure that all review activities are executed efficiently and effectively. Support periodic audits and regulatory inspections. Develop and implement systems to ensure inspection readiness. Provide data for departmental performance metrics. Serve as a Quality representative on cross-functional and multi-site teams. May be required to support other Quality Systems & processes such as Document Management, CAPA, Product Complaints, Annual Product Reviews. Support internal and partner audits, and health authority inspections.

### **Who You Are**

B.A. or B.S. degree (preferably in Life Science) and at least eight years of relevant experience in the pharmaceutical or biopharmaceutical industry, including three or more years of supervisory experience, or an equivalent combination of education and experience. Proven skills in building and maintaining strong professional relationships, specifically with diverse teams. Sound decision making skills Demonstrated ability to interpret and apply cGMPs, regulations and Quality standards within Change Control processes Flexibility in problem solving, providing direction, and work hours to meet business objectives Highly team oriented, self-motivated, well organized, and able to develop alternative solutions to issues Ability to communicate clearly and professionally both in writing and verbally

Genentech is an Equal Opportunity Employer.