

Technical Editor/Writer

Job ID: 00414263

Job Function

Production & Manufacturing

Schedule

Full-time

Location

United States-California
Vacaville

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

Create and edit controlled documents at all levels of complexity consistent with current formats and department style guides using the DocLink Electronic Document Management System (EDMS). Ensures document changes have been approved within the Trackwise Technical Change Management System. Ensure new, revised, retrieved, or temporary documents are in accordance with Quality Requirements and Global Standard & Processes. Ensure requirements for making document changes are met. Verify the changes being made to the document have been authorized in the change record. Initiate a document change workflow to execute a document change. Edit the document according to the change record. Perform final review of the document for consistency and completeness. Assign the appropriate document approvers. Collaborate with the Change Owner and Change Controller to resolve issues when a document is rejected. Ensure all document approval signatures have been obtained prior to releasing the document. Ensure all gating, training, and change deployment requirements outlined in the change record are considered when releasing the document and assign an effective date for the document. Maintain a master copy of all controlled documents released locally in a secure location. Support the Controlled Document Manuals (CDMs) and the Document Audit Reporting program. Evaluate and prioritize assigned document workload to meet internal productivity targets. Partner with other change control groups to coordinate changes with cross site impact.

Represent department on interdepartmental project teams. Track and communicate the status of document changes and projects. Enforce document and change control policies and procedures. Participate in document change control process improvement initiatives. Train new hires and internal customers, as appropriate. Support generating and presenting data for agency and third party audits.

Follow company policies and procedures. Maintain a state of inspection readiness.

Provide input to the development of personal performance goals and departmental objectives.

Collaborate with Management to establish and meet targets and timelines. Independently manage competing priorities with limited instruction. Serve as a Quality representative on cross-functional and multi-site teams. Identify and recommend solutions to potential procedure, process and system gaps. Provide assistance to customers in support of departmental functions. Participate in the design and implementation of department and cross-functional initiatives. Apply basic theory and technical principles to address moderately complex problems.

Troubleshoot and initiate 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. Sign documents for activities as authorized and 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.

Who You Are

QUALIFICATIONS: EDUCATION, EXPERIENCE, KNOWLEDGE AND SKILLS:

- B.A. or B.S. degree (preferably in Life Science) and at least 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.