

Senior QA Specialist

Job ID: 00413987

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

Main Purpose of the Position:

- Manage and develop solutions to complex global QC change control issues and Quality initiatives with inter-organizational and multi-site impact across the Biologics network following cGMP regulations and Roche standards.
- Perform tasks and work to achieve company goals and organizational objectives.

Job Duties/Responsibilities:

- Follow company policies and procedures.
- Set personal performance goals and provide input to departmental objectives.
- Establish work priorities to meet targets and timelines.
- Manage competing priorities and allocate, adjust, and optimize assigned department resources.
- Serve as the Quality representative on cross-functional and multi-site teams.
- Identify, design, and implement process and system improvements.
- Manage department and cross-functional initiatives.
- Apply advanced theory, technical principles, expert judgment, and cross-functional expertise to independently address a broad range of complex 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.

- Develop and train personnel and internal customers on relevant business processes.
- Mentor junior personnel serving as a subject matter expert (SME) on Quality systems, processes and issues.
- Collaborate and author department policies and procedures.
- Make decisions that impact the goals and objectives of the department.
- Notify Management of potential quality or regulatory issues that may affect product quality or regulatory compliance.
- Sign documents for activities as authorized and described by Roche policies, procedures and job descriptions.
- Be accountable for behaviors as described in Roche Leadership Competencies.
- Perform any other tasks as requested by Management to support Quality oversight activities.

Technical Duties/Responsibilities:

- Manage the end to end change control process.
- Manage multi-site change control activities for the Biologic OU including but not limited to; Specifications, direct materials, validated systems, methods, qualified equipment, and controlled documents.
- Manage the Review and approve processes for changes.
- Ensure system and process changes are reflected in appropriate procedures and controlled documents.
- Collaborate with internal departments and across sites to ensure understanding and execution of change control process and procedures.
- Facilitate and contribute to cross-site change management forums.
- Develop and implement strategies for effectively managing multi-site changes
- Lead change control process improvement activities
- Promote and provide guidance in Good Documentation Practices.
- Assist in developing training content and qualifications for change control processes and change management applications.
- Serve as a resource for Change Control knowledge management across site Quality departments.
- Collaborate with Quality departments in the administration, access, and communication of the Change Control system.
- Manage Record Management and Record Retention program activities and processes.
- Manage the centralized records repository.
- Collaborate with Operational and Quality departments to maintain GMP records.
- Provide metrics and reporting as needed.

Who You Are

B.A. or B.S. degree (preferably in Life Science) and at least eight years experience in the pharmaceutical, biopharmaceutical or related industry, or an equivalent combination of education and experience

- Sound knowledge of cGMPs or equivalent regulations
- Knowledge of Biotech manufacturing operations and Quality Systems.
- Sound knowledge of cGMPs
- Ability to interpret and relate Quality standards for implementation and review
- Ability to make sound decisions about scheduling, allocation of resources, managing priorities, and Quality issues.
- Excellent communication skills to communicate in writing and verbally on global level
- Flexibility in problem solving, providing direction and work hours to meet business objectives
- Ability to work collaboratively across a global organization

- Demonstrated ability to influence others

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