

## Biochem and TMC MQA, Technical Manager/Sr. Technical Manager

Job ID: 00414308

**Job Function**

Quality Assurance

**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

Level - E3/E4

**Main Purpose of the Position:**

- Solve a wide range of difficult Manufacturing Quality Assurance and Product Release issues that impact multiple functions following cGMP regulations and Genentech standards
- Perform assigned tasks and work to achieve company goals and department objectives.

**Job Duties/Responsibilities:** • 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.
- Support routine operations and allocate assigned resources.
- Manage competing priorities.
- 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 and internal customers on relevant business processes.
- 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.

#### Technical Duties/Responsibilities:

- Manage the product disposition program in support of manufacturing operations.
- Review and approve master batch production records.
- Collaborate with departments to ensure product release activities are executed efficiently and effectively.
- Review and approve lot release documentation.
- Provide technical assessment for process changes that may impact product disposition.
- Provide Quality oversight to internal and external customers.
- Provide input into investigations with potential product, process, or material impact.
- Ensure process and documentation discrepancies are identified, defined and assessed.
- Recommend final product disposition impacted by a deviation or discrepancy to Senior Management.
- Create and maintain a system for tracking, trending, and reporting discrepancies identified and assessed by MQA.
- Develop a system for tracking, trending, and reporting product release cycle times.
- Monitor MQA activities to evaluate trends, and report repetitive anomalies, observations, and discrepancies to Senior Management.
- Represent MQA at cross-functional meetings to develop, review, and approve Commercial Quality documents.
- Participate in the MQA review audit program and the Raw Material Reconciliation process.
- Present and provide rationale for the batch release program during periodic audits and regulatory inspections.
- Prepare, review, and approve relevant sections of regulatory submissions.
- Ensure proper department policies and procedures are in place to execute MQA and Product Release functions.
- Provide input into the design and presentation of department performance metrics.

#### Who You Are

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

- Sound knowledge of cGMPs or equivalent regulations
- 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

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