

QA Associate II

Job ID: 00414253

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

Main Purpose of the Position:

- Provide day to day support to Non-Commercial Filling and Finishing Operations.
- Solve routine Manufacturing Quality Assurance and Product Release issues with broader scope and increased complexity following cGMP regulations and Genentech standards.
- Perform assigned tasks and work to achieve company goals and department objectives.
- Perform routine Manufacturing Quality Assurance tasks to support product manufacturing and release.

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.
- 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.

Technical Duties/Responsibilities:

- Evaluate and close complex, non-investigational discrepancies.
- Initiate discrepancy investigations as required.
- Draft and route discrepancy summaries to Discrepancy Management.
- Perform Assessor and Evaluation activities defined in the Discrepancy Management System (DMS).
- Review and close completed evaluations and perform additional activities as warranted in the Discrepancy Management Systems (DMS).
- Review, edit and approve controlled documents.
- Assess and summarize complex process deviations.
- Collaborate with internal and external departments on MQA and Product Release projects and commitments.
- Monitor MQA activities to evaluate trends, and report repetitive anomalies, observations, and discrepancies to Management.
- Represent MQA at cross-functional meetings to develop, review, and approve Commercial Quality documents.
- Independently manage daily activities in order to meet standard lead times.

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**

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