

Supervisor, Quality Control

Job ID: 00414087

Job Function

Quality Control

Schedule

Full-time

Location

United States-California
Vacaville

Job type

Regular Employee

Company/Division

Pharmaceutical

Job Level

Manager with Direct Reports

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:

- Supervise and develop Environmental Quality Control and Microbiology (EQCM) staff that perform routine and moderately complex testing activities and follow cGMP regulations and Genentech standards.
- Supervise performance and development of direct reports to ensure achievement of organizational and department goals and a productive environment.

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 personal goals for staff and provide regularly scheduled feedback

throughout the year. Ensure staff receives appropriate knowledge and skill development and growth opportunities.

- Assign activities to staff.
- Routinely monitor progress and completion of assigned staff activities.
- Supervise routine activities of moderate complexity.
- Notify Senior Management of potential quality or regulatory issues that may affect product quality or regulatory compliance.
- Sign documents for activities as authorized and described by Genentech policies, procedures and job descriptions.
- Be accountable for behaviors described in Genentech's Core, Common and Critical Competencies.
- Follow proper safety precautions and laboratory technique in the use of reagents and other chemical compounds, including but not limited to acetonitrile, chlorine, acids and bases, biologic toxins, microorganisms and potent compounds.
- Meets scheduled performance of 95% on time.
- Perform any other tasks as requested by Senior Management to support Quality activities.

Technical Duties/Responsibilities:

- Provide technical and compliance guidance on test methods.
- Review, evaluate and approve test data against established criteria.
- Provide input for the resolution of Out of Specification (OOS), complaints, discrepancies and Corrective and Preventive Actions (CAPA). Design testing strategy to support investigation.
- Review technical / investigation reports and provide input as requested.
- Identify potential improvements to Quality Control systems and procedures gaps, and implement improvements as directed.
- Provide guidance and coaching in the application of cGMP throughout Quality Control operations.
- Receive and provide training.
- Participate in collaborations to support complex and/or multi-site projects.
- Participate in internal and external audits and regulatory inspections.
- Provide input and guidance to authors of protocols and reports.
- Review and approve proposed changes to systems, test procedures, test methods, procedures and submissions to regulatory agencies.
- Participate in validation and qualification studies.

Who You Are

Qualifications: Education, Experience, Knowledge and Skills:

(Minimum requirements)

- B.A. or B.S. degree (preferably in Biological Science, Life Science, or Microbiology)
- At least five years' experience in Environmental Quality Control or related industry, or an equivalent combination of education and experience
- Knowledge of cGMPs strongly preferred

- **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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