

Manager, Commercial Drug Product Manufacturing QA

Job ID: 00414174

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:

- Lead the planning, preparation, and conduct of Quality Assurance staff performing a variety of routine and complex oversight activities that meet cGMP regulations and Genentech standards.
- Lead DP MQA performance and development of direct reports to ensure achievement of organizational and department goals and a productive environment.

Job Duties/Responsibilities:

- Coach and develop staff by providing an environment that encourages ongoing personal and professional development. Manage and ensure the setting of realistic goals for staff and provide regularly scheduled feedback throughout the year. Ensure staff receives appropriate knowledge and skill development and growth opportunities.
- 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.
- Accountable for systems to ensure any non-compliant events occurring in

Manufacturing are assessed in a timely manner in compliance with Quality policies and Health Authority expectations.

- Accountable for systems to ensure documentation is reviewed in a timely manner and with a high level of accuracy.
- Guide staff in meeting goals by identifying and completing assignments.
- Recommend and implement improvements to Quality operational policies, plans and procedures.
- Manage routine department activities and complex Quality initiatives.
- Ensure activities and initiatives are completed on time and within budget.
- Maintain capacity model to ensure appropriate resourcing of the area.
- Present complex quality issues and potential solutions at site leadership teams (QRB, Quality Council, SMART)
- Monitor and control expenditures against the department budget.
- Notify Senior Management of potential quality or regulatory issues that may impact product quality or regulatory compliance.
- Lead and participate in continuous improvement initiatives for Roche Quality Systems.
- Sign documents for activities as authorized and described by Roche policies, procedures and job descriptions.
- Be accountable for behaviors described in Roche's values and Leadership Competencies.
- Perform any other tasks as requested by Senior Management to support Quality oversight activities.

General:

- As required, serve as a Quality liaison with regulatory agencies and external sources regarding issues impacting quality assurance manufacturing.

Manufacturing Quality Assurance/Environmental Quality Assurance:

- Represent MQA as the prime internal and external contact on contracts and operations.
- Guide staff in supervising and integrating quality oversight into manufacturing operations.

Who You Are

Qualifications (Education, Experience, Knowledge, Skills):

- B.A. or B.S. degree (preferably in Life Science) and eight years of relevant experience in the pharmaceutical or biopharmaceutical industry, including three or more years of supervisory experience, 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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