

Sr. Manager Quality Engineering Validation (QEV)

Job ID: 00414720

Job Function

Management Quality

Schedule

Full-time

Location

United States-California
South San Francisco

Job type

Regular Employee

Company/Division

Pharmaceutical

Job Level

Manager

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

Manage selection, hiring and training of personnel on company and department policies, systems and processes. Manage and communicate compensation related information per company guidelines.

- Ensure effective training program exists, improve with time, and are managed in compliance with PQS
- Ensure all employees have developmental goals and barriers removed to support attainment of goals
- Drive continuous improvement initiatives which simplify processes, enabling improvement in right-first-time, and appropriate prioritization of high compliance risks
- Manage and prioritize resources through IMPACT and in alignment with associated IMPACT prioritization principles
- Ensure projects and initiatives are completed on time and within budget.
- Collaborate, influence and/or author department policies and procedures.
- At the cross-site and corporate level, provide leadership, vision and direction to:
 - address complex validation issues and influence network direction
 - develop and maintain validation programs within cGMP regulations and the PQS.
- Monitor and control expenditures against the department budget.
- Immediately escalate potential quality or regulatory issues that may impact product quality

or regulatory compliance.

Technical Duties/Responsibilities:

- Provide direction to subordinates in order to provide effective oversight of all validation systems lifecycle deliverables, per PQS.
- Interpret, implement and recommend improvements to validation policies, procedures, processes and workflows to meet quality and business objectives.
- Ensure that the Quality Leadership Team is aware of significant validation issues that may impact product quality or operations.
- Maintain and present validation systems health, representing the health of the program.
- Serve as technical and strategic resource for a range of validation assignments.
- Review and approve regulatory submissions and present validations to regulatory authorities during routine and pre-approval inspections.

Who You Are

B.A. or B.S. degree (preferably in Life Science) and twelve years relevant experience in the pharmaceutical or biopharmaceutical industry, including five 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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