

QA Senior Specialist

Job ID: 00414411

Job Function

Quality Systems

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

Purpose:

- Solve a wide range of difficult validation activities and quality issues that impact multiple functions following cGMP regulations and company standards.
- Identify gaps and declining trends as well as innovate on processes and tools to simplify work and standardize practices.
- Build relationships and teamwork across departments, functions, and organizations to ensure commitment and adherence to PTQ strategies and initiatives.
- Be open-minded to diversity in people and ideas and be customer focused without sacrificing quality.
- Perform assigned tasks and work to achieve company goals and department objectives.

Accountabilities:

- Innovate and develop tools and processes to improve standard work and efficiencies.
- Build relationships to influence and disseminate PTQ strategies, processes, and initiatives.
- Proactively identify gaps and trends in quality and compliance in order to proactively prevent decrease in compliance for inspections.
- Be open to diverse opinions, ideas, and viewpoints to be in a position to make the best decisions, plan, and executions.
- Balance between customer service and compliance without sacrificing quality standards and quality of work.

- Establish and follow company policies and procedures.
- Maintain a state of inspection readiness.
- Provide input to the development of personal performance goals and departmental objectives.
- Establish work priorities to meet targets and timelines.
- Manage competing priorities and allocate, adjust, and optimize assigned resources when applicable.
- Serve as the Quality representative on cross-functional and multi-site teams.
- Identify, design, and implement process and system improvements.
- Development and manage department and cross-functional initiatives.
- Apply advanced theory, technical principles, expert judgment, and cross-functional expertise to independently address a broad range of complex 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.
- Develop and train personnel and internal customers on relevant business processes.
- Mentor junior personnel serving as a subject matter expert (SME) on quality systems, processes and issues.
- Collaborate on and author department policies or guidelines.
- Make decisions that impact the goals and objectives of the department.
- Notify Management of potential quality or regulatory issues that may affect product quality or regulatory compliance.
- Be accountable for behaviors as described in companies Core, Common, and Critical Competencies.
- Perform any other tasks as requested by Management to support quality oversight activities

Requirements:

- Process Change Requests related to accountable computer systems.
- Determine Change level per quality policies and appropriate training.
- Review, assess and approve IT related changes.
- Collaborate with departments to ensure validation activities are executed efficiently and effectively.
- Provide guidance to internal and external customers on best practices for executing and maintaining a validation program.
- Develop strategies for new validation projects in collaboration with system owners.
- Develop near-term and long-range plans for the group in collaboration with Management.
- Review and approve applicable validation deliverables.
- Collaborate with departments to ensure validation activities are executed efficiently and effectively.
- Present and provide rationale for the validation strategies during internal and external audits.
- Ensure the department is represented on relevant project teams.
- Identify, design, and implement validation process improvements.
- Support internal and external audits.
- Assist senior personnel in support of regulatory inspections
- B.A. or B.S degree (preferably in Life Science or Engineering) and at least ten 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

- Ability to assess gaps and trends in quality and compliance and to propose to execute process improvements and tools for simplification and harmonization.
- Ability to build teamwork and relationships within the department and with various departments and org units and open to diversity in people, culture, and ideas.

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Genentech is an Equal Opportunity Employer.