

QA Product Technical Manager/Sr. QA Product Technical Manager

Job ID: 00413341

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

The Position

- Perform final review, cumulative review and disposition of Genentech manufactured cell banks and clinical drug substance, drug product and final drug product.
- Review and approve procedures, tickets and other clinical QA controlled documentation.
- Provide clinical trial support such as COA/COC/COT requests.
- Provide support and oversight of manufacturing activities on the floor.
- Manage batch disposition activities to ensure that products are dispositioned in accordance with cGMPs, Regulatory, and Genentech Policies and Procedures and adherence to schedule.
- Set personal performance goals and collaborate with management to establish organizational objectives.
- Manage competing priorities to meet department and organizational targets and timelines.
- Serve as the Quality representative on cross-functional and multi-site teams.
- Identify, design, and implement process and system improvements.
- Apply advanced theory, technical principles, and judgment to address a broad range

of difficult problems.

- Notify Management of potential quality or regulatory issues that may affect product quality or regulatory compliance
- 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.
- Interface with appropriate departments to ensure that batch disposition items are complete and timely notification to Management of all known delays and significant Quality issues is provided
- Interact with interdepartmental contacts on discrepancy assessment, resolution, and Quality approval
- Support and present in Internal and Regulatory Inspections.
- Participate in the resolution of Quality issues by fostering effective interdepartmental and cross-functional relationships.
- Participate or lead different internal or cross functional projects relevant to QA lot disposition
- Train new personnel and internal customers on relevant business processes.
- Ability to revise or create work instructions, SOPs and business process instructions.

Who You Are

Qualifications: Education, Experience, Knowledge and Skills:

- B.A. or B.S. degree (preferably in Life Science) and at least 10 years of experience in the pharmaceutical, biotechnology or related industry or an equivalent combination of education and experience
- At least three years of large molecule batch record review/batch release experience
- Having knowledge of DS, DP, and FDP manufacturing processes is a plus
- Familiarity with SAP system for lot release is a big plus
- Must be capable of applying cGMP concepts and requirements to evaluate product disposition using sound judgment and decision-making skills.
- Sound knowledge of cGMPs and regulations applicable to U.S. and international Regulatory agencies.
- Proven ability to interpret and relate Quality Standards for implementation and review
- Proven ability to make sound decisions regarding scheduling, allocation of resources and managing priorities
- Being able to communicate well both verbally and in writing
- Experience with project management is a plus

- Flexibility in problem solving, providing direction and work hours to meet business objectives
- Flexible to travel for business needs (less than 5%)

Genentech is an Equal Opportunity Employer.