

Technical Manager, Lot Disposition

Job ID: 00411582

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 QA Product Technical Manager is the key point of contact for all issues affecting the disposition of their assigned product(s). This individual will be responsible for interacting with multiple departments within Roche to assure that all lot disposition issues are identified and resolved within standard lead times.

- Perform assigned tasks and work to achieve company goals and department objectives.

Job Duties/Responsibilities:

- Follow company policies and procedures.
- Maintain a state of inspection readiness.
- Provide input to the development of personal performance goals and departmental objectives.
- Collaborate with Management to establish and meet targets and timelines.
- Support routine operations and allocate assigned resources.
- Manage competing priorities.
- Serve as the Quality representative on cross-functional and multi-site teams.
- Identify, design, and implement process and system improvements.
- Lead and participate in the design and implementation of department and cross-functional initiatives.
- Apply advanced theory, technical principles, and expert judgment to address a broad range of difficult 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.
- Train personnel and internal customers on relevant business processes.
- Sign documents for activities as authorized and described by Genentech policies, procedures and job descriptions.
- 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.

Technical Duties/Responsibilities:

- Oversight of the activities associated with dispositioning of assigned production lots within established standard lead times.
- Management of lot disposition activities to ensure that products are dispositioned in accordance with regulatory requirements, cGMPs and Genentech policies and procedures, within established standard lead time.
- Interfacing with appropriate departments or manufacturing plants to ensure that lot disposition items are completed.
- Notification to Senior Management for all known delays in meeting established standard lead times or any potential significant quality issues.
- Interfacing with QA Lot Disposition Supervisors and Final Reviewers to ensure that final review activities are completed. Lead and provide guidance to Final Reviewers as required.
- Perform a review of investigations for potential cumulative effect to a batch history record.
- Perform a review of QC out of trend results for cumulative effect.
- Provide assistance to CMC teams by addressing lot disposition issues as they arise.
- Support regulatory inspections as needed.
- Assess batch history records as part of investigations into product complaints.
- Revise and approve applicable lot disposition documents as needed.

Who You Are

B.A. or B.S. degree (preferably in Life Science) and at least five 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

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