

Sr. Technical Manager, Global Complaint Management

Job ID: 00411009

Job Function

Other Quality

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

- Follow company policies and procedures and be accountable for behaviors as described in Genentech's Core, Common, and Critical Competencies
- Lead product complaint investigations with minimal guidance and ensure investigation action plans and final investigation summaries are accurate, include appropriate corrective actions, and follow company standards.
- Apply advanced theory, technical principles, expert judgment, and cross-functional expertise to independently address a broad range of complex problems.
- Develop solutions to complex product complaint issues and Quality initiatives with inter-organizational impact following cGMP regulations and Genentech standards.
- Ensure appropriate application & integration of cGMPs in the product complaints management system.
- Set personal performance goals and provide input to departmental objectives.
- Establish work priorities to meet targets and timelines and manage competing

priorities/

- Serve as the Quality representative on cross-functional and multi-site teams.
- Identify, design, and implement process and system improvements.
- Troubleshoot and direct the resolution of Quality issues by fostering effective interdepartmental and cross-functional partnerships.
- Develop, train, and mentor personnel and internal customers on relevant business processes.
- Collaborate and author department policies and procedures.
- 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.
- Inform management of critical product complaints and provide timely impact assessments of potentially affected products, materials or processes.
- Review and approve product complaint investigation reports and supporting documentation.
- Lead collaboration with departments to establish appropriate, efficient, and timely investigation strategies.
- Educate departments on the best practices for conducting investigations and root cause analysis.
- Lead project teams to resolve deficiencies identified through the root cause analysis process.
- Assess the accuracy of root cause determinations based on a thorough evaluation of possible failure modes.
- Present product complaint records and/or reports during periodic audits and regulatory inspections.
- Perform any other tasks as requested by Management to support Quality oversight activities

Who You Are

- B.A. or B.S. degree (preferably in Life Science) and at least eight years' experience in relevant field(s), e.g., Pharmaceutical/biopharmaceutical experience, quality management, pharmacy, nursing
- Sound knowledge of cGMPs or equivalent regulations
- Sound knowledge of product complaint handling associated with [Small Molecules/Biologics] products.
- Ability to interpret and relate Quality standards for implementation and review
- Ability to communicate clearly and professionally both in writing and verbally
- Ability to make sound decisions about scheduling and managing priorities
- Flexibility in problem solving, providing direction, and work hours to meet business needs

- Demonstrated ability to understand and organize technical data for communication and analysis

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