

Prin Technical Mgr Ext Quality

Job ID: 00410841

Job Function

Administrative Assistance

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:

This Principle Technical Manager will manage the Quality oversight related to sterile diluents manufactured at a Contract Manufacturing Organization (CMO) located in North Carolina.

This person will be a key member of the CMO governance team to support right to operate and supply of diluents packaged with several critical Genentech/Roche products.

Responsibilities:

- Influence and drive Right to Operate and continuous improvement to achieve compliant and reliable supply of diluent for Roche products.
- Establish and monitor CMO Quality goals and metrics to drive continuous improvements
- Recommend, implement, and drive strategic objectives and goals of the CMO relationship
- Facilitate issue resolution and problem solving within CMO site, with

Roche/Genentech functional departments supporting Contract Manufacturing, and through the agreed project governance structure as appropriate.

- Manage the release of product, including batch record review, investigations, change controls
- Partner with the CMO to ensure proper aseptic control during Roche operations
- Observe end-to end production activities that include filling, terminal sterilization, visual inspection, and labeling
- Work with CMO to align requirements for visual inspection of diluent
- Make decisions if issues arise during production
- Support validation activities, product complaint investigations, creation of Annual Product Reviews, and other quality functions as required
- Develop/maintain quality risk management plans and risk logs; utilize risk management tools to identify and mitigate CMO quality and compliance risks
- Ensure that CMO meets Roche Pharmaceutical Quality Standards (PQS)
- Participate in regulatory inspections and GNE compliance audits
- Develop and negotiate Quality Agreement with CMO
- Support any regulatory filings for diluent manufactured at CMO
- Present quality topics to varying governance bodies, such as Quality Review Boards, Operational Review Meetings, and Roche/CMO Steering Committees
- Serve as the Quality representative on cross-functional and multi-site teams

Who You Are

B.A. or B.S. degree (preferably in Life Science) and at least twelve years experience in the pharmaceutical, biopharmaceutical or related industry, or an equivalent combination of education and experience

- Sound knowledge of cGMPs, aseptic processing and packaging operations
- Ability to interpret Quality standards for implementation and review
- Ability to communicate clearly and professionally both verbally and in writing
- Excellent decision making, negotiation and influencing skills especially with external partners
- Travel between 25-50%

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