

Principal Technical Manager

Job ID: 00411345

Job Function

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

Lead process improvement projects at supplier sites as part of Supplier Management process, CMO light

Working with Genentech technology transfer teams lead:

- Raw material transfers to CMOs
- Raw material transfer from customers (insourcing projects)

Responsible for SAP management as an SME; provide updates and training of the group in the areas of Supplier and management of raw materials

Responsible for managing, negotiating and completing Quality agreements with suppliers

Duties/Responsibilities:

- Troubleshoot and direct the resolution of raw material Quality issues by fostering

effective interdepartmental and cross-functional partnerships. Provide solutions to complex manufacturing, quality and negotiation problems.

- Develop project plans and establish work priorities to meet targets and timelines.
- Identify, design, and implement process and system improvements.
- Manage department and cross-functional initiatives and activities.
- Apply, technical principles, expert judgment, and cross-functional expertise to independently address a broad range of complex problems related to chemical and component materials.
- Serve as a technical subject matter expert (SME) in raw material and component requirements/specifications review and approval.
- Serve as a trainer and train internal personnel (as needed) on SAP processes related to raw material management.
- Collaborate and author department policies and procedures.
- Be able to make decisions using a collaborative and cross functional process
- Be able to apply good judgment and notify and escalate to Management potential quality or regulatory issues that may affect product quality or regulatory compliance.
- Author, review and approve technical reports as a result of projects
- Be accountable for behaviors as described in Genentech's Core, Common, and Critical Competencies.
- Set personal performance goals and provide input to departmental objectives.
- Manage competing priorities and allocate, adjust, and optimize assigned department resources.
- Perform any other tasks as requested by Management to support Supplier Quality oversight activities of chemical and component suppliers.

Technical Duties/Responsibilities:

Work with internal, CMO and customer groups and lead the tech transfer of raw materials.

In partnership with GNE's critical and standard suppliers ensure uninterrupted supply and internal raw material management groups perform the following technical duties. .

- Review Supply agreements and implement Quality Agreements with suppliers (as applicable)
- Lead and or participate in Business and performance review meetings as applicable
- Participate in supplier Risk Assessments, and Supplier Analysis with Procurement (as

applicable)

- Lead supplier site technical visits to review entire manufacturing processes related to manufacturing of chemicals, components and diluent materials
- Partner with supplier on internal audits (when possible)
- Perform supplier audits as needed
- Write and review technical reports
- Represent GNE in customer advisory boards
- Design and issue supplier business and Quality reports annually
- SME representative in the SAP team

Who You Are

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- B.A. or B.S. and M.S. degree in Chemistry/Chemical Engineering/ Biochemistry 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, ISO standards and international regulations
- Ability to interpret and relate Quality standards as they related to Genentech and suppliers
- Ability to make sound quality and manufacturing decisions with an E2E approach
- Ability to communicate clearly and professionally both in writing and verbally
- Candidate must be able to build relationships cross functional and with outside companies
- Must have project management experience and the ability to lead complex projects
- Must possess proven negotiation skills and the ability to influence GNE's suppliers and internal groups
- Must have knowledge of chemical manufacturing processes, laboratory test methods, validation processes
- Knowledge of OE tools desired; i.e. statistical methods, FMEA, Six Sigma, Lean
- Expert level knowledge of SAP, LIMS, and FileMaker desired.
- Candidate must be able to travel approximately 10% of the time.

Genentech is an Equal Opportunity Employer.