

## Head of Small Molecule Products - North America, External Quality

Job ID: 00414085

### Job Function

Quality

### Schedule

Full-time

### Location

United States-California  
South San Francisco

### Job type

Regular Employee

### Company/Division

Pharmaceutical

### Job Level

Manager with Direct Reports

## 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:

The Head of Small Molecules Development Products, North America, in External Quality is accountable for the development and deployment of the Quality strategy for the selection and operation of Contract Manufacturing Organizations (CMO) that support the gRED Small Molecules development portfolio. Accountable for all aspects of Quality related to these CMOs to include: Quality Systems, Product Quality Operations, Process Qualification and Validation, cGMP Compliance, Risk Management, GMP Audit and Inspection Readiness. Responsible for ensuring that all GMP activities are in the best interest of the patients, comply with global regulations and uphold Roche's reputation as a reliable, high quality supplier of IMP products. In collaboration with other PTx and gRED functions, ensures appropriate measures are employed to fulfill the requirements of phase appropriate cGMPs, international standards and requirements. Responsible for risk management utilizing risk management tools for each CMO within group's scope. Accountable for the management of Quality and Compliance within the group to include: staffing, talent management, performance management, financial performance, and execution to meet strategic and

operational objectives.

Responsibilities:

- \* Management of the North America Small Molecule Development Products Group
- \* Staff and assign Quality Managers to lead quality teams for IMP products after approval to proceed to development utilizing CMO manufacture
- \* Lead Quality Managers in the implementation and execution of Quality processes for the selection, implementation, and ongoing management of development CMOs
- \* Accountable for the Quality and Compliance Status for all CMOs within the group's scope of operations
- \* Establish and manage performance metrics for the Key Performance Indicators (KPI)
- \* Determine staffing requirements and provide input to department budget
- \* Establish individual goals for direct reports, provide performance management for direct reports, and conduct talent management in accordance with Roche standards and procedures
- \* Accountable for the deployment of the Roche PT Pharmaceutical Quality System (PQS) standards and requirements for outsourcing for all Small Molecule Development CMOs used for the gRED portfolio, ensuring appropriate risk assessment and mitigation for identified gaps
- \* Participate in Joint Steering Committees through the established Governance processes as required. Define quality actions to be resolved and/or escalated to Roche senior management at the Executive Steering Committees.
- \* Accountable for approval of:
  - \* Quality Agreements Appendices, such as PSRs, for Development CMOs on behalf of Roche Quality
  - \* IND and IMPD Manager Level reviews
  - \* Major Deviations or Changes in Roche Approval systems

## **Who You Are**

Requirements:

(Minimum requirements)

- \* Bachelors, Masters or Ph. D degree (Chemistry/Chemical Engineering/Other Science preferred). At least 12 years experience in pharmaceutical in mfg, quality assurance or quality control. At least 5 years of management or project experience in a quality role. At least 3 years experience in operating quality systems in bio-pharmaceutical operations
- \* Strong knowledge of cGMP and Quality requirements for various early and late phase clinical stages
- \* Experience in technical aspects of pharmaceutical manufacture (Starting materials,

intermediates, API, Solid Dosage Forms, and Packaging)

- \* Demonstrated track record of sound decision-making about scheduling, allocation of resources, prioritization as well as Quality and Compliance decisions

- \* Demonstrated negotiation and influencing skills

- \* Demonstrated communication skills both in writing and verbally

- \* Travel Requirements: Approximately 25% travel domestic and international

- \* Location: South San Francisco

Genentech is an Equal Opportunity Employer.