

Principal Engineer

Job ID: 00414735

Job Function

Production & Manufacturing

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

Responsibilities:

This position is for a Principal Engineer/Principal Manufacturing Technical Specialist reporting to the Associate Director of Technology Validation in the South San Francisco Production Technology Department. The candidate will independently lead highly complex compliance and transformational validation program projects. The candidate will also be expected to lead site implementation of complex multi-site CAPAs and quality system deployments. These projects require close collaboration with site Manufacturing, MSAT and Quality and other functions as well as network colleagues and corporate quality functions over the course of multiple years. This candidate will sit on the Technology Validation Leadership Team and will assist the Associate Director in developing group goals and development plans. The candidate must provide mentorship and direction to staff on interpretation of the Roche Quality System requirements, execution of the Qualification Lifecycle and Qualification Strategies for highly complex projects. This candidate will also be responsible for representing Genentech in agency inspections and audits. They will participate in network teams developing quality system approaches.

Who You Are

Education:

A B.S. or higher in Chemical, Biochemical or Mechanical Engineering or related discipline with 12-15+ years of relevant experience. An M.S., M.B.A. or other advanced technical or

business degree is desirable.

Requirements:

The candidate is expected to be a recognized authority in the field of Validation and/or compliance. The candidate must have demonstrated capability to effectively manage complex projects in a GMP environment. They must possess an expert understanding of the requirements of a GMP regulated industry. They must have the capability to independently develop innovative solutions to highly complex challenges, while applying sound technical judgment to sustain and improve our compliance position. They will be expected to draw on their knowledge of Validation and their network of resources to deliver transformational business process and systems. The candidate will be expected to foster teamwork, and work collaboratively. They will often act as a consultant to management on Validation issues and will be expected to act as a spokesperson to advocate not only for assigned projects but the Validation function as a whole. The candidate must be comfortable with change and be willing to establish and work towards the future vision for the organization.

Physical Requirements: The candidate must be able to lift and carry 25 lbs. The candidate must be able to climb and descend stairs. The candidate must be able to don gowning as required to enter GMP facilities.

Genentech is an Equal Opportunity Employer.