

## Principal Technical Mgr, Validation

Job ID: 00410444

### Job Function

Quality Systems

### 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

Level: E4/E5

The position is for a recognized expert and leader as it relates to process and cleaning validation and operations with the ability to gain alignment, advise, coach and train. This includes expertise in the principles and approaches of process and cleaning validation, and is responsible for leading the continued development, implementation and execution of the process and cleaning programs meeting health authority requirements. The Principal Technical Manager will develop solutions to complex Quality system and governance issues and initiatives with inter-organizational impact following cGMP regulations and Roche standards.

- Recognized expert and leader as it relates to process and cleaning validation and must have the ability to gain alignment, advise, coach and train Validation and Operations personnel with respect to process and cleaning validation requirements.
- Expertise in the principles and approaches of process and cleaning validation, leading the continued development, implementation and execution of the process and cleaning programs meeting health authority requirements.
- Develop solutions to complex Quality system and governance issues and initiatives with inter-organizational impact following cGMP regulations and Roche standards.
- Identify and implement solutions to complex Quality system governance concerns and

improvement opportunities with multi-site and inter-organizational impact.

#### Key Accountabilities:

- Provide Process and Cleaning Validation and Operations expertise to develop, implement, and sustain PQS requirements in accordance with worldwide GMP regulations and Roche standards.
- Act as Global Coordinator for the development, deployment and implementation of the PQS Product and Process Lifecycle and associated global standards and processes.
- Adhere to Roche's Quality philosophy and utilize PQS business process and applicable Quality systems, i.e., CAPA and Technical Change Management tools.
- Apply advanced theory, technical principles, expert judgment, and cross-functional expertise to independently address a broad range of complex problems.
- Troubleshoot and direct the resolution of Quality issues by fostering effective interdepartmental and cross-functional partnerships.

#### Who You Are:

- Collaborative Leadership – Looks for opportunities to help others. Works well in a collaborative team environment and communicate effectively with customers, peers, and senior management. Demonstrates respect and appreciation for a diversity of perspectives. Maintains professionalism in presence of conflict.
- Technical Leadership – Demonstrates ability to provide technical leadership and teamwork in a GxP environment across functional and organizational boundaries.
- Ownership and Accountability – Takes accountability for actions, drives results, and learns from mistakes. Holds oneself accountable to fulfill assigned tasks and achieve results within timelines. Initiates additional assignments and assumes responsibilities as appropriate. Determines methods and procedures on new assignments.
- Communication – Is thorough in capturing all relevant information in communications. Conveys concepts and positions clearly, with straightforward language, both verbally and in writing. Readily grasps the main points in communication from others. Asks questions for clarification.
- Planning/Organization – Responds to new requests with appropriate urgency and with an organized approach.
- Problem Solving – Identifies problems, defines problem statement clearly and accurately, and applies structured and disciplined methodology to identify root causes. Is effective in solution development, risk mitigation, stakeholder buy-in, and execution.
- Customer Focused – Partners with customers and looks ahead to predict future customer needs. Manages expectations.
- Technology Platform Experience – Has exposure to and expertise in multiple GxP environments. Executes work in collaboration with multiple technical disciplines.

#### Who You Are

B.A. or B.S. degree and at least ten years experience in the pharmaceutical, biopharmaceutical or related industry, or an equivalent combination of education and experience

- Sound knowledge of EU, US, Japan, and ICH GMPs
- Expertise in process and/or cleaning validation and operations
- Practical experience with Quality Systems development
- Strong collaboration skills across cultures, countries, and organizational levels
- Ability to communicate clearly and professionally both in writing and verbally
- Flexibility in problem solving and providing direction to meet business objectives.

Genentech is an Equal Opportunity Employer.