

## **Sr. Quality Engineer - IMP Quality Assurance**

Job ID: 00413520

### **Job Function**

Quality Assurance

### **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**

- Provide QA oversight, support and execution of validation/qualification activities pertaining to Investigational Medicinal Products (IMP, a.k.a. clinical) GMP manufacturing equipment and analytical instruments, including preventive maintenance and requalification activities.
- Provide technical review and approve quality risk management and validation/ qualification deliverables for small molecules and biologics equipment qualification, ensuring proper design and execution.
- Ensure that equipment and systems remain in a validated state, and that validation master plans and their related documents are accurate and current.
- Develop strategies and act as project manager for new projects in collaboration with system owners.
- Develop near-term and long-range plans for the department in collaboration with Senior Management.
- Provide technical assessment and approval for GMP changes.
- Assess equipment-related discrepancies and provide input to investigations.
- Apply expertise of compliance requirements to maintain an inspection-ready state.
- Participate in audit/inspections as a subject matter expert.
- Support implementation and provide stakeholder feedback and input to the integrated Pharmaceutical Quality System (PQS) documents.
- Perform tasks and work to achieve company goals and organizational objectives.

- Serve as the Quality representative on cross-functional and multi-site teams.
- Provide guidance to internal and external customers on best practices for generating and executing validation protocols.
- Provide input into investigations involving GMP related failures.
- Develop and implement process and system improvements, including contributing to the development of new concepts, techniques and standards.
- Advise other IMP QEV staff members on Validation related processes and projects.
- Supervise/oversee temporary or contract staff, as required.

## **Who You Are**

### **Job Requirements:**

- B.A., B.S., M.S., Ph.D. degree (preferably in Life Science) and at least 10 years experience in the pharmaceutical, biopharmaceutical or related industry, or an equivalent combination of education and experience
- Sound knowledge of local and global cGMP requirements as well as internal PQS requirements
- Strong background in Quality Systems and Validation supporting both Biologics and Small Molecules (preferred).
- Ability to make sound decisions about scheduling, allocation of resources, and managing priorities
- Ability to communicate clearly and professionally both in writing and verbally

Genentech is an Equal Opportunity Employer.