

## Senior Engineer-Validation

Job ID: 00414583

### Job Function

Technical Functions and Maintenance

### Schedule

Full-time

### Location

United States-Oregon  
Hillsboro

### 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

Under the direction of the Technical Validation Associate Director the Senior Engineer will be accountable for leading teams and performing validation activities such as Performance Qualification (PQ) / Cleaning Validation (CV) / Process Validation (PV) and Revalidation (RV). Able to collaborate with both plant and all network organizations seamlessly. Is constantly in search of the most creative and innovative solutions to maintaining the highest levels of productivity. Is able to provide the leadership necessary to maintain a high performance culture Responsibilities: Develop and manage the detailed project plans and timelines for the execution of validation activities. Prepare validation & change control documentation, including protocols, summary reports, etc., for validation activities. Act as project manager for validation teams ensuring new systems are implemented within predetermined timelines and financial forecasts. Present and provide rationale for the validation program during periodic audits and regulatory inspections. Procure and manage contractor support for outsourced validation and risk management assignments. Support the change management system for validated equipment, utilities and facilities. Prepare, review and approve relevant sections of regulatory submissions. Serve as a risk management representative on cross-functional and multi-site teams to support integrating risk management into various Product Quality Systems (PQS) such as, Discrepancy Management, Change Control and CAPA. Lead and facilitate Risk Assessment sessions. Provide input into investigations and change control with potential impact to the site risk profile. Foster an environment that encourages continuous learning. Maintain expertise as necessary to stay abreast of technical and industry advancements. Mentor more junior

validation engineers and train individuals on practices and procedures.

**Who You Are**

BS/MS in chemical, biochemical engineering, or related field/experience, with a minimum of 8+ years experience in drug product Process Research & Development, Engineering, Manufacturing, or Technical Services is required. Experience in the pharma/biotech industry is a plus. Knowledge of cGMPs or equivalent regulations. Working knowledge of formulation, filling, and, packaging, equipment qualification in a regulated environment is preferred. Demonstrated project management skills. Ability to work with internal teams, partners, suppliers and customers. Operational excellence and industrial engineering skills are a plus. Professional level written and oral communication skills.

Genentech is an Equal Opportunity Employer.