

Engineer I-Validation

Job ID: 00414590

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 MSAT Technical Services Manager, the Engineer I, Validation will be accountable for validation activities such as Performance Qualification (PQ) / Cleaning Validation (CV) / Process Validation (PV) and Revalidation (RV) activities. Candidate will be able to collaborate with both plant and corporate organizations seamlessly, will be constantly in search of the most creative and innovative solutions to maintaining the highest levels of productivity and will be able to provide the leadership necessary to maintain a high performance culture. Responsibilities: Develop, execute, and manage the detailed project plans and timelines for the execution of PQ/CV/PV/RV activities. Plan and execute PQ/CV/PV/RV 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. Provide input into investigations with potential validation impact. Present and provide rationale for the validation program during periodic audits and regulatory inspections. Procure and manage contractor support for outsourced validation assignments. Coordinate the collection, testing and analysis of samples and reporting of results required per validation protocol. Support the change management system for validated equipment, utilities and facilities. Prepare, review and approve relevant sections of regulatory submissions. Serve as a representative on cross-functional and multi-site teams. Lead and facilitate the development of formulation, filling, and packaging, area SOP's and manufacturing documents as appropriate. Foster an environment that encourages continuous learning. Maintain expertise as necessary to stay abreast of technical and industry advancements.

Manage the development and implementation of novel approaches to solving complex technical problems while maintaining required levels of safety, quality (including regulatory compliance), and production.

Who You Are

BS/MS in chemical, biochemical engineering, or related field/experience. Minimum of 2 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. 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.