

IT Quality Assurance - Sr Validation Engineer

Job ID: 00409753

Job Function

Information Technology

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

The role of the Validation Engineer, located in San Francisco, is a trusted partner for customers to ensure and improve the overall quality of IT systems throughout their lifecycle with a focus on compliance with regulatory, legal and finance requirements. We are looking for a customer-focused, highly collaborative individual to work with delivery units to advance existing emerging business critical technology according to Roche Pharma needs.

The selected candidate will be responsible to:

Participate in the development of new standards and revision of existing standards related to Computer Systems Validation (CSV). This includes, but not limited to policies, directives, and Global Informatics standard operating procedures related to the CSV area.

Assemble global feedback on proposed or existing standards and tools and providing recommendations for new guidance/standards or revisions to existing guidance/standards.

Provide consultation and guidance to delivery and operational units within Pharma IT to provide accurate interpretation of Roche CSV approach and requirements, information

concerning regulatory requirements related to CSV in the specified area, updates on changes in the regulatory environment

Assure that processes are established across Pharma IT to support delivery and operations of compliant systems.

Gather and analyze metrics and key performance indicators to identify opportunities for process improvement

Escalate non-compliance against quality standards to appropriate governance bodies and Risk Management function for resolution

Facilitate and leverage quality practitioners within the delivery units to identify best practices, and lead improvement initiatives across functional areas

Identify new training programs and/or revisions to existing training programs and approaches for delivery of training within and outside of Global Informatics

Provide change request control and support for legacy GMP systems

Who You Are

For this position, you bring the following qualification:

BS in Computer Science, engineering or equivalent degree and/or experience

5 - 8 years of professional IT experience in global regulated organization

Knowledge of Health authority regulations, Risk Management, GxP classification, SDLC, Data classification, documentation standards, Infrastructure Qualification, CSV, Change management principles

Experience in working in a regulated environment and with Computer System Validation

Ability to travel as required up to 25% - Advanced English reading, writing, speaking and listening skills

Genentech is an Equal Opportunity Employer.