

Software Quality Assurance (SQA) Analyst

Job ID: 00394049

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 TrackWise Center of Excellence is looking for a highly skilled Computer Systems Validation (CSV) and Software Quality Assurance (SQA) analyst able to perform within the multicultural team supporting numerous GxP TrackWise processes. We are seeking an expert in GxP computer validation, 21 CFR Part 11 and Annex 11 requirements, and possessing excellent interpersonal, communication and critical thinking skills.

Job Responsibilities:

- Provide estimates and forecasting for CSV and SQA project resource needs
- Assist in developing and approving computerized systems requirements and functional specifications
- Create GxP deliverables such as validation master plans, test plans, installation, operation and performance qualifications (IQ\OQ\PQ), test scripts, validation summary reports, risk control strategies and risk assessments for changes to validated systems
- Conduct system testing for emergency, and maintenance and enhancement releases
- Document and provide feedback to development teams on issues and bugs identified during testing
- Maintain accurate bug tracking and issues resolution logs
- Develop and execute manual and/or automated test documentation in accordance with approved processes and established standards, and in compliance with

- applicable regulatory expectations
- Document test results and work with development teams to resolve test deviations; perform root cause analyses
- Develop new processes and process improvements
- Coordinate with cross-functional teams including Quality to ensure accuracy of all testing documentation
- Partner with development teams to support installation activities and configuration management
- Escalate issues and deviations as needed to management
- Provide subject-matter expertise on software quality assurance best practices, regulatory expectations and 21 CFR Part 11 and Annex 11 requirements
- Liaison with Quality to ensure compliance with corporate policies and procedures (SOPs)
- Oversee contract validation personnel

Who You Are

For this position, you bring the following qualifications:

- Bachelor's degree or equivalent work experience in computer sciences, software engineering or similar
- Experience in the development, maintenance and support of validated applications within FDA and EMEA regulated (GxP) environments
- 5 - 9 years of professional IT experience with focus on Quality and CSV
- Experience writing GxP validation deliverables
- Experience with Project Management, CSV, and Software Development Lifecycle Models in the healthcare industry
- Fluent English skills (written and spoken)
- Strong verbal communication and technical writing abilities
- Flexibility working outside normal working hours to support global implementations across different time zones

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