

Senior Pharmaceutical Computer System Validation Specialist

Job ID: 00407033

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

Job Duties/Responsibilities

- Leads the development, planning, directing and tracking of the validation of GxP computer systems operated by North American ERP team (i.e. SAP ERP, BW, APO, XI, Solution Manager, GRC, Portal and Business Objects).
- Responsible for the quality systems and processes that ensure computer systems are operated and maintained a validated state. This includes all modifications and / or changes to systems or processes, change control, periodic revalidation activities and ensures a continual state of inspection readiness with regard to cGxP's.
- Leads the Information Technology and Quality team members to develop and implement validation strategies in accordance with company policies, directives and government regulations.
- Develops and writes validation project plans, master validation protocols, acceptance criteria traceability matrices and summary reports by providing instructions and scientific rationale for the performance of validation studies.
- Leads fellow technical and analysis team members in ensuring quality systems and processes are in compliance with corporate quality directives, policies, standards and procedures.
- Responsible for the maintenance of departmental quality systems and procedures to assure compliance with new and revised corporate standards and policies.

- Coordinates the testing efforts of the IT and business teams with regards to requirements, resource planning, test coverage, test strategies for the orth American SAP systems.
- Coordinates and interacts with all affected personnel in the execution of test scripts and validation protocols and gathering of test data. Ensure all protocol executions are documented and recorded in accordance with company quality policies, quality standards and SOPs.
- Reviews and approves validation data to assure protocol acceptance criteria is achieved and all deviations are completed and recorded according to procedures.
- Ensure all final reports are completed according to procedure.
- Coordinate and manage the application release cycle processes.
- Manage the life cycle documentation.
- Recommends methods for process improvement, detailing process strengths and weakness of existing and proposed procedures and controls
- Participate in internal and external vendor audits and regulatory audit teams.
- Define and maintain GxP training program to support compliance requirements for IT staff.

Who You Are

Qualifications

- Minimum of Bachelor's degree in Sciences or Computer Science discipline.
- Minimum of 5 years of experience supporting validating computer systems and software testing in Pharmaceutical or Bio-Tech industry is required (regulated by government agencies such as FDA, EMEA, Japan Health Authorities, Canadian Health Authorities, etc).
- Participation in at least one full life-cycle SAP implementation and post implementation support is required.
- Excellent working knowledge of government regulations (FDA, EMEA, Japanese Health Authority) pertaining to computer systems validation (CFR Part 11) and cGxPs is required.
- Must be able to clearly present ideas, opinions and facts. Solid negotiating skills.
- Excellent written communication skills.
- Strong commitment to customer service and satisfaction are essential.
- Experience presenting validation data in external government regulatory audit/inspection teams, is preferred.

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