

Equipment & Cleaning Validation Technical Manager

Job ID: 00412191

Job Function

Production & Manufacturing

Schedule

Full-time

Location

United States-California
Oceanside

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

Responsible for implementing and maintaining the validated state of equipment, IQ,OQ,SIP and cleaning validation programs. Expected to be knowledgeable of and work within GMP regulations. Requires protocol generation, execution, data analysis, troubleshooting skills, deviation investigation and protocol report closure for the site. Responsible for validation contractor oversight, demonstrating leadership skills and modeling Genentech values and core competencies while working closely with Engineering, MSAT, Quality Assurance and Manufacturing. This position requires strong communication and collaboration skills, the ability to work within teams, facilitate meetings and lead teams.

- Manage and track the Validation program and assigned validation projects and ensure target
- timelines are met and/or issues are communicated / escalated effectively and consistently.
- Generate, review, approve and maintain Validation Project Plans and Summary Reports and other validation lifecycle documents.
- Generate, review and approve a variety of Validation protocols (IQs, OQs, IOQs, PQs, SIP, CV) for equipment.
- Manage protocol execution, perform data review and manage deviation resolution.
- Oversight and management of validation contract resources including work

- prioritization, execution and contractor budget.
- Strong understanding of commercial production environment and requirements.
- Evaluate and audit the current validated status of equipment/systems temperature mapping and cleaning validation program.
- Proven ability to make suggestions for improvements as well as ensure programs are operating in a compliant and validated state.
- Present validation packages as required for audits and/or regulatory inspections.
- Perform role of subject matter expert and assess change control and discrepancy events for to validated systems.
- Review validation lifecycle documents for compliance with CFRs, corporate policies (QP/QS documents), and site procedures (SOP's).
- Participate in cross-functional team meetings and where required, lead/facilitate meeting.
- All employees with jobs that require access to the Warehouse must be able to pass the Transportation Security Administration (TSA) Security Threat Assessment (STA).
- Ensures there will be integration of environmental health, safety, and security into the business processes, systems, and programs while reporting safety and environmental incidents including injuries, illnesses, and safety suggestions within their functional area.

Who You Are

- BS degree in Engineering, Biology or relevant scientific discipline.
- 4-6 years combined engineering/validation/project management experience in a federally regulated industry.
- Minimum of 4 years validation experience in the pharmaceutical/biotechnology industry.
- Minimum of 3 years hands-on experience with equipment / utility / data review and analysis in a batch manufacturing environment.
- Hands-on experience commissioning/validating GMP equipment/utilities preferred.
- Knowledge, skills and abilities
- Sound knowledge and understanding of GMP guidelines, USP, and CFRs applicable to the pharmaceutical/biotechnology industry.
- Ability to manage technical projects through to completion and direct resources (e.g. contractors) to achieve results.
- Logically and methodically works through complex problems to identify root causes and provide rational solutions.
- Ability to influence project team members, customers, Quality, and Engineering/MSAT in order to successfully execute and complete validation projects.
- Establishes self as an individual sought-out for their knowledge, experience, and judgment.
- Proven effective verbal and written communication skills.
- Ability to present and defend validation program and strategy to peers, management, internal groups and regulatory authorities.
- Delivers results and does not allow adversity or unplanned challenges from preventing successful completion of projects and goals.
- Understands the validation process and recognizes supplier limitations and customer expectations.
- Accountable for projects, decisions, and communication.
- Seeks guidance and support when required.
- Subject matter expert in system validation with proven ability to improve the process.
- Understands validation team goals and seeks opportunities to achieve team success.

- Supportive of peers and willing to share knowledge and mentor others.

Genentech is an Equal Opportunity Employer.