Senior/Principal Technical Manager, Validation

Job ID: 201909-127861

Job Function
Quality Validation

Location
Vacaville
California
United States of America

Company/Division
Pharmaceuticals

Schedule
Full time

Job type
Regular

Job Level
Individual contributor

The Position

Summary

The Quality Engineering and Validation (QEV) department provides quality oversight of the equipment, facility and utility systems, computerized systems, and manufacturing processes throughout the systems qualification lifecycle, and product and process lifecycle. The team partners with our customers to design, implement and qualify/validate systems and processes, and apply industry standards and best practices to ensure our engineering, qualification and validation processes remain current and complaint. QEV is responsible for ensuring effective site engineering, qualification and validation programs are developed, implemented and maintained in accordance with the Roche Pharmaceutical Quality System (PQS), health authority requirements, and industry standards. The team’s quality oversight responsibilities include engineering, maintenance, calibration, equipment, facilities and utilities qualification, process automation qualification, process validation, cleaning validation, sterilization validation, computerized system validation, shipping qualification, technology transfers, and process and product monitoring.

This position is for a Senior Technical Manager/Principal Technical Manager reporting to the Head of Quality Engineering and Validation in the Quality department. This position provides quality oversight of GMP computerized systems including engineering, maintenance, and the system qualification lifecycle activities such as process automation qualification, computerized system validation, computerized system controls, the supervisory control of equipment, facilities and utilities, technology transfers, installation of new computerized systems, replacement of existing computerized systems, and modifications to existing qualified computerized systems.

The candidate will work on cross-functional project teams, providing quality support in the delivery of expense/capital projects and engineering changes at the Vacaville Manufacturing Facility. The candidate will also lead the development, implementation, and continuous improvement of an optimized business process for the quality oversight of GMP computerized systems in partnership with our customers. This position will primarily support the oversight of GMP computerized systems used in the Genentech Vacaville Cell Culture
Plant 2 facility, and site-wide GMP computerized systems.

**Job Responsibilities**

**Technical and Functional:**

- Ensure current Good Manufacturing Practice (cGMP) regulations and Roche PQS requirements are met for the qualification and maintenance of GMP computerized systems
- Provide quality oversight of engineering, qualification and validation activities
- Apply knowledge of qualification and validation principles, manufacturing processes, quality systems, engineering design fundamentals, health authority expectations, and industry standards
- Serve as qualification/validation expert for GMP computerized systems
- Review and approve qualification and validation documents
- Participate in technical change management process as change assessor
- Approve Standard Operating Procedures and other documents as described by Roche policies and procedures
- Provide technical knowledge and expertise to support quality investigations and CAPAs involving GMP computerized systems
- Support the resolution of quality issues by fostering effective cross-functional partnerships
- Support health authority inspections, and internal and partner audits
- Influence the development, revision and implementation of local and global Roche PQS documents in alignment with health authority expectations, and industry standards and best practices for GMP computerized systems
- Represent department on interdepartmental project teams fostering effective cross-functional partnerships
- Ensure leadership is regularly updated on significant engineering, maintenance, qualification, validation, and computerized system controls issues
- Participate in site and Roche network activities to standardize qualification and validation approaches, and address complex qualification and validation issues
- Establish, maintain, and leverage effective partnerships with Roche network counterparts to share best practices and influence the design and implementation of our network policies, standards, and processes
- Lead and participate in continuous improvement efforts, including leading the development, implementation, and continuous improvement of an optimized business process for the quality oversight of GMP computerized systems in partnership with our customers
- Collaborate with engineers, system owners, process owners, and Validation to design, build, and test new GMP computerized systems to ensure the systems reliably meet their intended use
- Partner with the Validation and Process Automation departments to ensure qualification/validation testing is performed effectively and efficiently
- Partner with Process Automation and Pharma Informatics to ensure GMP computerized systems are reliably maintained
- Assess the impact of changes to the qualified state of GMP computerized systems during the operate and maintain phase
- Provide technical input and oversight of the periodic qualification review process to ensure a GMP computerized system's qualified state is maintained
- Maintain a state of inspection readiness
Solve a wide range of challenging qualification/validation and maintenance issues that impact multiple functions in alignment with cGMP regulations and Roche PQS requirements

**Job Requirements**

**Education:**
- BA/BS or higher degree in engineering or life sciences

**Experience:**
- Minimum of 8-12 years of work experience in the biopharmaceutical industry in the fields of engineering or qualification/validation
- Minimum of 5 years of work experience in the qualification of manufacturing computerized systems in the biopharmaceutical industry
- Experience with requirements definition, system design, implementation, and qualification/validation of manufacturing execution systems and batch control systems in 21 CFR Part 11 compliant GMP manufacturing environments in the pharmaceutical industry
- Experience with distributed control systems, programmable logic controllers, implementation of ISA S88 batch control system standard, software development methodologies, and automated system lifecycle support in the pharmaceutical industry
- Experience with quality risk management and risk based validation approaches

**Knowledge/Skills/Competencies:**
- Sound knowledge of health authority regulations and guidances, including U.S. Code of Federal Regulations, European Union EudraLex, and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines
- Strong quality mindset and knowledge of quality system principles, practices and standards for the pharmaceutical industry
- Thorough understanding of industry standards and best practices for computer system validation/qualification such as ISPE GAMP 5, ISPE Baseline Guide: Commissioning and Qualification, and ASTM E2500
- Strong knowledge of operations and qualification/validation of biopharmaceutical manufacturing facilities, systems and processes
- Must have excellent interpersonal, communication, and teamwork skills
- Capable at building trustful and effective relationships
- Able to evaluate situations, apply critical thinking skills, and propose potential solutions
- Able to think strategically and translate strategies into actionable plans
- Able to make sound decisions about quality and technical subjects
- Acts as a change agent who can drive transformational change
- Takes responsibility, drives results, and achieves expected outcomes
- Demonstrates excellent verbal and written communication skills and the ability to influence at all levels
- Flexibility in problem solving and work hours to meet business objectives

#PT100

#ptcareers

**Who We Are**

A member of the Roche Group, Genentech has been at the forefront of the biotechnology
industry for more than 40 years, using human genetic information to develop novel medicines for serious and life-threatening diseases. Genentech has multiple therapies on the market for cancer & other serious illnesses. Please take this opportunity to learn about Genentech where we believe that our employees are our most important asset & are dedicated to remaining a great place to work.

Genentech is an equal opportunity employer & prohibits unlawful discrimination based on race, color, religion, gender, sexual orientation, gender identity/expression, national origin/ancestry, age, disability, marital & veteran status. For more information about equal employment opportunity, visit our Genentech Careers page.