Genentech
A Member of the Roche Group

Date: 09/10/19

Senior Quality Control Associate I

Job ID: 201909-125899

Job Function
Quality Control

Location
Hillsboro
Oregon
United States of America

Company/Division
Pharmaceuticals

Schedule
Full time

Job type
Regular

Job Level
Individual contributor

The Position

Responsibilities include performing technical and compliance laboratory related activities that support QC operations. Manage and execute method transfers, method qualifications, equipment qualifications, data review, gap assessments, gap remediation, and discrepancy and out-of-specification investigations. Lead troubleshooting of assay failures and equipment issues. Collaborate with external groups to identify improvement opportunities in analytical technology and business processes.

Responsibilities:

- Lead method transfers/method validations and prepare method transfer/validation protocols and summary reports
- Function as HTO QC point of contact for analytical questions pertaining to assigned products
- Apply advanced theory, technical principles, and expert judgment to address a broad range of difficult problems
- Plan and execute equipment qualification activities and generate, review, or approve equipment qualification/maintenance life cycle documents
- Lead or participate in the identification, design and implementation of department and cross-functional initiatives and set personal performance goals
- Identify and drive closure of gaps in systems and procedures
- Identify, design, and implement process and system improvements
- Manage and close discrepancies, lead and conduct out of specification/out of expectation/over limit investigations, and define and complete corrective actions preventive actions (CAPA), as needed
- Identify and troubleshoot technical problems
- Review data and assess against established acceptance criteria
- Evaluate data to identify trends and/or establish limits
- Perform technical review of peer-generated data
- Support peer development by providing coaching and mentorship

- Lead or participate in multifunctional teams/groups, projects, and process improvements
- Provide and receive training and support development and administration of Quality Control training materials.
- Support the maintenance and compliance of operational areas and apply GMP throughout all quality control operations
- Support internal and external audits and regulatory inspections
- Establish work priorities to meet targets and timelines; manage competing priorities
- Serve as the Site QC representative/technical subject matter expert (SME) on cross-functional or multi-site teams and coordinate with customers to support multi-site operational activities
- Notify Management of potential quality or regulatory issues that may affect product quality or regulatory compliance
- Be accountable for behaviors as described in the Roche leadership commitments
- Perform any other tasks as requested by Management to support Quality oversight activities

Qualifications: Education, Experience, Knowledge and Skills:

- B.S./B.A. degree and ten plus years of experience or Master's degree plus five years' experience or an equivalent combination of education and experience. Degrees are preferably in Chemistry, Biochemistry, Microbiology or relevant scientific discipline and experience is in pharmaceutical or biopharmaceutical industry.
- Sound knowledge of cGMPs or equivalent regulations
- Technical proficiency in quality systems
- Strong verbal and written communication skills, ability to organize and present information informal and formal group setting.
- Demonstrated ability to apply knowledge of scientific theories, principles, and techniques used in analytical or biological test procedures.
- Ability to make sound decisions about allocation of resources and managing priorities.
- Ability to interpret and relate Quality standards for implementation and review.
- Flexibility in problem solving, providing direction and work hours to meet business objectives.
- Ability to troubleshoot instrumentation.

Work Environment/Physical Demands/Safety Considerations

- Work in office and laboratory environment.
- Lift up to 25lbs may be required.
- Ability to sit, stand and move within work space for extended periods.
- May be required to sit at a computer terminal for extended periods.

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.

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