

100537 Qc Pharm Spl II

Job ID: 00411867

Job Function

Quality

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

Note: Position can be filled as a QC Pharmaceutical Specialist II (E4) or Sr. QC Pharmaceutical Specialist (E5) based on education and experience.

QC Pharmaceutical Specialist II Role

The QC Pharmaceutical Specialist is a member of the senior technical staff of the QC Microbiology/Environmental/Molecular team specializing in environmental/utility monitoring support for biotech drug substance production and aseptic filling.

Main Purpose of the Position:

- Develop solutions to complex Environmental/Utility monitoring activities and issues.
- Lead Quality initiatives with inter-organizational impact following cGMP regulations and Genentech standards.
- Perform tasks and work to achieve company goals and organizational objectives.

Job Duties/Responsibilities:

- Follow company policies and procedures.
- Set personal performance goals and provide input to departmental objectives.
- Establish work priorities to meet targets and timelines.
- Manage competing priorities and allocate, adjust, and optimize assigned department resources.

- Serve as the Quality representative on cross-functional and multi-site teams.
- Identify, design, and implement process and system improvements.
- Manage department and cross-functional initiatives.
- Apply advanced theory, technical principles, expert judgment, and cross-functional expertise to independently address a broad range of complex problems.
- Troubleshoot and direct the resolution of Quality issues by fostering effective interdepartmental and cross-functional partnerships.
- Serve as a technical subject matter expert (SME) for Environmental/Utility Monitoring in support of department functions.
- Develop and train personnel and internal customers on relevant business processes.
- Mentor junior personnel serving as a subject matter expert (SME) on Quality systems, processes and issues.
- Collaborate and author department policies and procedures.
- Make decisions that impact the goals and objectives of the department.
- Notify Management of potential quality or regulatory issues that may affect product quality or regulatory compliance.
- Follow proper safety precautions and laboratory technique in the use of reagents and other chemical compounds, including but not limited to acetonitrile, chlorine, acids and bases, biologic toxins, microorganisms and potent compounds.
- Sign documents for activities as authorized and described by Genentech policies, procedures and job descriptions.
- Be accountable for behaviors as described in Genentech's Core, Common, and Critical Competencies.
- Meets scheduled performance of 95% on time.
- Perform any other tasks as requested by Management to support Quality oversight activities.

Technical Duties/Responsibilities:

- Provide technical expertise in the development of test method validation protocols and supporting procedures.
- Ensure validated methods and supporting procedures adhere to approved regulatory specifications.
- Prepare validation summary reports for test method validation activities.
- Provide input into regulatory filings.
- Participate in internal and external audits and regulatory inspections.
- Perform Quality Control testing for product release.
- Support quality investigations for testing and method discrepancies.
- Oversee equipment validation for laboratory instruments used in cGMP testing activities.
- Identify, initiate and approve change records to GMP controlled documents and electronic systems as appropriate.
- Collaborate with departments to ensure product release requirements are completed.
- Communicate testing, scheduling, or Environmental/Utility Monitoring issues that may impact the timely release of final product to Quality Control Management.
- Compile trending reports for method validation, testing activities and Environmental/Utility Monitoring.
- Develop and deliver training materials for new and revised test methods and laboratory procedures.

Who You Are

- B.A. or B.S. degree (preferably in Microbiology) and at least eight years experience in the pharmaceutical, biopharmaceutical or related industry with a minimum of 5 years specializing in Environmental/Utility Monitoring, or an equivalent combination of education

and experience

- Sound knowledge of cGMPs or equivalent regulations
- Ability to interpret and relate Quality standards for implementation and review
- Ability to make sound decisions about scheduling, allocation of resources, and managing priorities
- Ability to communicate clearly and professionally both in writing and verbally
- Flexibility in problem solving, providing direction and work hours to meet business objectives
- Proficiency with LIMS, Trackwise and Microsoft Office
- Thorough understanding of the rationale behind environmental/utility monitoring programs
- Expertise in regulations relating to Environmental/Utility Monitoring (Annex 1, EP/USP/JP and FDA Aseptic Processing Guidance)
- Expertise in assays/techniques used in Environmental/Utility Monitoring (Bioburden, Endotoxin, Conductivity, TOC, Viable and Non-Viable air monitoring)
- Working knowledge of Filemaker Pro, SAP and MES is a plus

Genentech is an Equal Opportunity Employer.