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Date: 11/07/19

Microbiology QC Scientist

Job ID: 201910-130564

Job Function
Quality Control

Location
South San Francisco
California
United States of America

Schedule
Full time

Job type
Regular

Company/Division
Pharmaceuticals

Job Level
Individual contributor

The Position

QC Scientist

The QC Scientist is a member of the senior technical staff of the Quality Control Microbiology (QCM) group. The QC Scientist will be responsible for developing rapid/alternative microbiological and endotoxin methods (e.g. Recombinant Factor C), troubleshooting microbiological method issues (including Low Endotoxin Recovery).

Main Purpose of the Position:

- Develop solutions to complex microbiology issues.
- Develop, implement, and maintain Quality Risk Management plans for QCM.
- Provide technical leadership to QCM staff.
- 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 Microbiology on local and global teams.

· 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.

· Review and approve reports as assigned

· Be accountable for behaviors as described in Genentech’s Core, Common, and Critical Competencies.

· 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 for rapid and automated microbiological methods and supporting procedures.

· Ensure validated methods and supporting procedures adhere to approved regulatory

requirements.

· Prepare validation summary reports for test method validation activities.

· Troubleshoot microbiological validation failures

· Provide input into regulatory filings and responsible for authoring submissions.

· 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 and Isolator technology, used in cGMP testing activities.

· Develop Design of experiment as needed, for but not limited to problem solving or investigation.

· Provide expertise for development of studies for Low Endootxin Recovery troubleshooting

· Provide expertise for development of Recombinant Factor C endotoxin method.

· Identify, initiate and approve change records to GMP controlled documents and electronic systems as appropriate.

· Provide guidance on data integrity for microbiological methods and stay up to date on industry requirements as related to microbiological methods.

· Collaborate with departments to ensure product release requirements are completed.

- Communicate testing, scheduling issues that may impact the timely release of final product to Quality Control Management.
- Develop and deliver training materials for new and revised test methods and laboratory procedures.

Qualifications: Education, Experience, Knowledge and Skills:

(Minimum requirements)

· Advanced degree in Microbiology (PhD preferred) with 6 - 9 years of experience in pharmaceutical microbiology (Masters) or 3 - 6 Years with PhD.

· Sound knowledge of cGMPs or equivalent regulationsfor microbiology

· Expertise in developing rapid/alternative microbiological and endotoxin methods (e.g. Recombinant Factor C) and troubleshooting microbiological method issues (including Low Endotoxin Recovery).

· Ability to interpret and relate Quality standards for implementation

- 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.

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.