Genentech
A Member of the Roche Group

Date: 12/07/18

Manager, QC Biochemistry

Job ID: 201812-129357

Job Function
Quality Control

Schedule
Full time

Location
United States of America - California
Oceanside

Job type
Regular

Company/Division
Pharmaceuticals

Job Level
Manager with direct reports

The Position

This role is responsible for developing, implementing and overseeing the daily operations of a Quality Control Biochem group and ensuring that the laboratory is maintained in a state of GMP compliance, while ensuring that all documentation is generated in accordance with GMP, and that all reported results are accurate. In addition, this role is responsible for all Quality Control Environmental and In-Process testing groups, and for ensuring that all reported results are accurate. Must plan, initiate, implement and oversee department activities with a focus upon ensuring attainment of department objectives. Provide performance management and career development for supervisory and/or technical staff.

Job Responsibilities

- Develop and implement operational, policy and procedural directives for area(s) of assigned responsibility.
- Plan, initiate, implement and oversee department activities with a focus upon ensuring attainment of department objectives.
- Provide performance management and career development for subordinate supervisory and/or technical staff.
- Review and approve recommendations and/or analytical QC data presented by subordinate(s)
  as appropriate.
- Coordinate with other departments and conduct investigations as an area expert for appropriate discrepancies.
- Participate with senior and executive management in the decision making process for capital equipment expenditures and the acquisition of new technologies.
- Investigate, develop and implement new and creative ways to accomplish department goals in the most cost effective and productive manner while maintaining high quality standards.

- Act as project leader to coordinate activities between divisions and provide scientific leadership.
- Represent department during FDA and/or Regulatory Inspections.
- Interact with FDA inspectors and other regulatory agencies to present and defend QC data.
- Develop and administer budgets, schedules and performance requirements for department, including accountability for results in terms of costs, methods and employees.
- Develop departmental strategic staffing plans and justifications for headcount and capital equipment requests.
- Review and approve recommendations and/or analytical QC data presented by subordinate(s) as appropriate.
- All employees with jobs that require access to the Warehouse must be able to pass the Transportation Security Administration (TSA) Security Threat Assessment (STA).
- Promotes a safety culture that support continuous improvement in the EHS management system through active communication and functional area participation in site safety teams ensuring the safe and efficient operation of assigned functional areas and activities.

Job Requirements

- Bachelor’s Degree in Biology, Microbiology, Biochemistry or other relevant Life Science discipline
- 9 years experience including 3 years in supervisory role
- Knowledge of industrial Biochemistry is essential.
- Demonstrate excellent project management skills including the ability to plan, prioritize and complete own work and the work of others.
- Experience supervising technical staff in a Quality Control and/or cGMP environment
- Familiarity with scientific disciplines outside of primary areas of expertise
- Demonstrate excellent project management skills including the ability to plan, prioritize and complete own work and the work of others.
- Demonstrate excellent personnel management and interpersonal skills including the ability to effectively collaborate with staff from other departments and representatives from regulatory agencies.
- Demonstrate strong presentation skills including the ability to prepare and deliver professional presentations to external business interests.
- Experience with laboratory operations
- Experience with sample management logistics
- Knowledge of cGMPs and other regulatory guidelines, ICH, EU .i.e.
- Experience with discrepancy management systems
- Demonstrates an understanding of QC laboratory operations
- Demonstrates an understanding of cGMP as they pertain to sample logistics
- Demonstrates good communication skills with a willingness to work in a team environment
- Understands discrepancy management process with emphasis on electronic systems
- Demonstrate excellent written and verbal communication skills.
- Ability to invest time to complete assignments as required.

- Demonstrate strong spreadsheet, word processing and database skills necessary to process and present technical data in a clear and concise manner.

This position is not eligible for relocation.

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.