

QC Associate II/Senior QC Associate

Job ID: 00414208

Job Function

Quality Control

Schedule

Full-time

Location

United States-California
Vacaville

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

Position may be filled at either the E2 or E3 level depending on qualifications of the selected applicant. The position will be in either the Raw Materials, Network Product Testing, Site Product Testing, Environmental Monitoring/Microbiology, or Lab Support Quality Control group and may require off-shift and weekend work schedule.

Main Purpose of the Position:

Perform analytical, biochemical, and/or biological testing; data review; and/or related activities that support QC laboratory operations.

Job Duties/Responsibilities:

- Perform testing of routine and non-routine samples and document according to GMP.
- Review data and assess against established acceptance criteria

- Perform technical review of peer-generated data for basic methods
- Prepare data tables and graphs
- Identify and propose resolution to discrepancies, participate in quality investigations and CAPA (corrective actions preventive actions) initiatives as needed.
- Receive and provide training
- Participate and provide input in assay transfer and assay validation.
- Perform equipment qualification / maintenance
- Prepare and maintain standards, controls, stocks, and cultures per established procedures
- Support the maintenance and compliance of operational areas.
- Assure and apply GMP throughout operations.
- Coordinate with customers to support operational activities.
- Support internal and external audits.
- Work to meet schedules.
- Identify and support resolution of technical problems.
- Actively participate and/or lead in group and project teamwork; project and process improvements.
- Drafts protocols and reports under supervision.
- Meets scheduled performance of 95% on time.
- Perform other duties as requested by managers to support Quality activities.

Who You Are

Qualifications: Education, Experience, Knowledge and Skills:

- B.S./B.A./M.S/M.A degree (preferably in relevant scientific discipline) and five to seven years of experience in the pharmaceutical or biopharmaceutical industry or an equivalent combination of education and experience.
- Demonstrated ability to apply knowledge of scientific theories, principles, and techniques used in analytical or biological test procedures.
- Consistently and independently exercises sound judgment, reasoning, and problem solving.
- Capable of working under minimal supervision and determining own short term priorities.
- Capable of completing assigned responsibilities and keeping manager informed of status.
- Strong verbal and written communication skills, ability to organize and present information both formally and informally.
- Demonstrated proficiency in technical writing.

Position may involve use of reagents and other chemical compounds, including but not limited to acetonitrile, chlorine, acids and bases, biologic toxins, microorganisms and potent compounds.

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