

Sr. Associate 1

Job ID: 00410801

Job Function

Quality Control

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: This position is posted as E3/E4 depending on skills and experience.

The job takes place in an office environment and requires computer use >4 h/day, prolonged sitting, and repetitive motion (keyboarding, mousing, etc.). Occasionally job requires lab investigation and potential exposure to a number of chemicals, including but not limited to: acetonitrile, chlorine, acids and bases, biologic toxins, microorganisms and potent compounds.

Main Purpose of the Position:

- Provide commercial and clinical product support to ensure highest level of compliance, uninterrupted supply to patient, and continuous improvement in business processes and

methods.

- Represent Quality Control in Product Quality Teams
- Draft Annual Product Quality Report and Annual Trend Report
- Ensure Quality Control is ready to execute commercial & clinical manufacturing campaigns
- Ensure effective corrective and preventive actions are systematically identified, analyzed, implemented and documented to prevent recurring problems and improve product and process quality.
- Perform tasks and work to achieve company goals and organizational objectives.

Job Duties/Responsibilities:

- Apply extensive theoretical and cross-functional expertise in the context of company objectives to independently address complex problems
- Subject matter expert in test methodology, systems, or operational process
- Review data and assess against established acceptance criteria
- Perform technical review of data derived from complex tests, including those outside their primary area of expertise
- Evaluate data to identify trends and/or establish limits
- Identify and resolve discrepancies. Design and execute quality investigations and CAPA (corrective actions preventive actions) initiatives as needed
- Review and approve technical / investigation reports.
- Identify, troubleshoot, and solve technical problems.
- Independently identify and lead process improvements and develop resolution of complex gaps.
- Provide input to and oversight for assay transfer and assay validation
- Act as a subject matter expert for equipment qualification and maintenance requirements, as assigned.
- Assure and apply cGMP throughout operations
- Design, develop, and/or approve training material. Receive and provide training as necessary.
- Lead collaborations to support complex and/or multi-site projects
- Serve as subject matter expert in internal and external audits and regulatory inspections
- Write protocols, procedures and reports
- Meets scheduled performance of 95% on time.
- Perform other duties as requested by managers to support Quality activities.
- Interacts with senior internal and external personnel on significant matters.
- Represents organization as a prime contact on initiatives and projects.
- May provide guidance and coordinate work activities of other personnel.

- Works on complex issues where analysis of situations or data requires an in-depth evaluation of variable factors, including inter-organizational impact.

Capabilities Identified for Success:

- Accountability
- Attention to Detail
- Communication
- Organization and Prioritization
- Policies, Process, Procedures
- Teamwork

Who You Are

- B.S./B.A. degree with minimum eight years experience or Masters degree with minimum six years experience, or PhD with minimum three years experience. Degrees are preferably in relevant scientific discipline and experience is in pharmaceutical or biopharmaceutical industry.
- Knowledge of applicable regulations: CFR , ICH, ISO, USP, JP and EP.
- 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 priorities.
- Proven verbal and written communication skills, ability to organize and present information both formally and informally.
- Demonstrated proficiency in technical writing.
- Demonstrated accountability / initiative

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