

Sr. Quality Specialist

Job ID: 00412538

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

- Manage Quality system for change control and document management functions for GMP changes involving equipment, documents, test methods, processes and specifications for IMP Small Molecule and Biologics operations.
- Manage workflow through Trackwise and EDMS to ensure timely release of systems and documents.
- Proactively identify, prioritize and assess quality systems compliance risks across the IMP network
- Manage Quality System for discrepancy and CAPA management for IMP customers.
- Perform routine Quality trend analysis of IMP discrepancies and audit of incident discrepancies.
- Manage workflow through Trackwise discrepancy and CAPA systems
- Manage and oversee GMP self inspection program for IMP manufacturing and testing areas including:
 - Maintain plan and schedule for self inspection audits
 - Coordinate self inspection audits with other subject matter experts.
 - Issue audit reports and track corrective actions from audits.
 - Communicate to PTQ-U leadership regarding compliance status
 - Provide Quality oversight to GMP IMP Contract Laboratories/Organizations.
 - Maintain list of approved contract testing laboratories and corresponding Quality

Agreements

- Provide support for establishing new Quality Agreements, revising or renewing existing Quality Agreements, and periodic review of Quality Agreements
- Participate in lab audits as needed
- Serve as the QA representative on cross-functional and multi-site teams.
- Facilitate continuous improvement and the sharing of best practices at the various IMP global sites
- Provide guidance to internal and external customers on best practices for various Quality Systems.
- Mentor and supervise (as required) other Quality System staff members on Change Control, Discrepancy, CAPA, Self-Inspection, and Quality Agreements and or related processes and projects.

Who You Are

- B.A., B.S., M.S., Ph.D. degree (preferably in Life Science) and at least 8 - 11 years experience in the pharmaceutical, biopharmaceutical or related industry, or an equivalent combination of education and experience
- Extensive knowledge of local and global cGMP requirements
- Experience supporting production and testing of investigational medicinal products (IMPs)
- Strong background in Quality Systems.
- Ability to interpret and relate Quality standards for implementation and review, and apply Quality, compliance, and risk concepts to make sound technical decisions.
- Ability to make sound decisions about scheduling, allocation of resources, and managing priorities.
- Ability to communicate clearly and professionally both in writing and verbally

Genentech is an Equal Opportunity Employer.