

QC Scientist/Pharmaceutical Specialist II

Job ID: 00407383

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

The QC Pharmaceutical Specialist will be a member of the Method Transfer, External QC, and Method Monitoring group, which is part of ROCHE/GENENTECH's Global Method Management and Technology (Global MMTech), the department responsible for the life cycle management of all commercial methods and control systems and innovation within Commercial Biologics Quality.

Method Transfer, External QC, and Method Monitoring is responsible for all aspects of assay transfer, QC support of CMOs and partners, and method monitoring activities across ROCHE/GENENTECH's entire commercial network, including CMOs and partners. The successful candidate will provide QC oversight of Contract Manufacturing Organizations (CMOs) who manufacture and test commercial ROCHE products.

Job Responsibilities:

The successful candidate will be responsible for managing all QC aspects at our CMOs on a global basis as the single point of contact representing ROCHE/GENENTECH. The scope of this role includes all US based CMOs that manufacture and test Commercial Small Molecule Pharmaceutical Products. Responsibilities include, but are not limited to, the following key aspects: Qualify CMO for QC testing and data review; ensure appropriate adherence to cGMP requirements at CMO; work with appropriate subject matter experts to provide support to CMO in QC related investigations and analytical method issues; participate in laboratory audits and inspections; participate on Quality Review Boards as needed; manage change

control for all CMO analytical methods and laboratory impacting activities; review and approve documents; manage critical reagents/reference standard supplies for CMOs; support preparation of Annual Product Quality Reports.

Who You Are

A Ph.D. degree in Analytical Chemistry, or related fields with at least 5 years of industry experience, or a MS degree with at least 8 years of industry experience, is required.

A solid background in analytical technologies for small molecule drugs and previous experience working in the pharmaceutical industry in Quality Control or one or several of the following areas is required - Quality, analytical sciences, pharmaceutical development, manufacturing, or process development.

Previous experience working in a cGMP environment, preferably in a Commercial Quality Department is required.

Highly motivated and self-driven individual with the ability to work under minimal supervision to schedule, track, review and report on complex Method Transfer Activities per established guidelines and timelines.

Ability to work closely with internal departments, partners and CMOs including the senior management on significant matters concerning projects and commitments.

Effective in problem solving and negotiation skills to meet business objectives in a highly dynamic global business environment.

Ability to communicate clearly and professionally both in writing and in speaking.

Experience in project management and/or project leadership in a complex matrix environment is required.

Good team player and collaboration skills are highly desirable.

Previous experience in working with external parties (CMOs, Contract Labs) is preferred.

Ability to travel to support audits or site management activities (up to 20%) both domestically and internationally.

Genentech is an Equal Opportunity Employer.