

Senior QC Scientist/Scientist, Analytical Chemistry

Job ID: 00399656

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 candidate will be a member of the Analytical Chemistry group in the Method Management and Technology (MMTech) Function within Genentech's Corporate Quality Organization. MMTech is the scientific and technical Center of Excellence for commercial quality control methods, specifications/control systems and reference standard and provides support to the Roche/Genentech Global Quality Control Network for the commercial biotech product portfolio. We are looking for an experienced Scientist to play an integral part in providing and supporting analytical chemistry methods (e.g. HPLC, CE) used for quality control purposes.

MAIN PURPOSE OF THE POSITION

- Responsible for method troubleshooting and optimization in support of life-cycle management of methods for Roche/Genentech commercial biotech products
- Develop and execute experiments for the development, validation, implementation of QC test methods for commercial biologic products following cGMP regulations, regulatory guidelines as well as local and global quality standards.

- Support regulatory submission and inspections: through authorship of CMC subsections, responses to questions and direct interactions

JOB DUTIES/RESPONSIBILITIES

- Serve as analytical technical lead/representative (biotech products) on cross-functional and multi-site project teams.
- Ensure on-time delivery of controlled documents, reports and method packages to support project timelines.
- Apply technical knowledge, scientific experience and expert judgment to address a broad range of difficult problems.
- Troubleshoot and direct the resolution of QC method issues by fostering effective interdepartmental and cross-functional partnerships.
- Serve as a technical subject matter expert (SME) in support of departmental functions.
- Perform assigned tasks and work to achieve company goals and department objectives.
- Train personnel and internal customers on relevant business processes.
- Support the development and administration of Quality Control and laboratory training materials.

Who You Are

- Candidates must have a Ph.D. in Analytical Chemistry or other scientific field with demonstrated experience (a minimum of 4 years) or alternatively a BS or MS degree with at least 6-10 years of experience.
- Candidate must also have extensive knowledge and experience in biotechnology QC method development and validation, methods troubleshooting and lifecycle management.
- A strong background and in depth knowledge in analytical chemistry across a wide range of technologies (HPLC, CE etc.) is necessary.
- Strong planning and project management skills are necessary.
- Excellent skills in teamwork and collaboration with international and external partner organizations are required.
 - Strong knowledge of cGMP, regulatory requirements and analytical control strategy for pharmaceuticals is necessary.
 - Direct experience with various regulatory bodies (written submissions etc.) is highly desirable.
 - Strong communication (written and verbal) and presentation skills are a must.
 - Some travel may be required.

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