Genentech
A Member of the Roche Group

Associate Scientist/Scientist, GC-MS/LC-MS/Leachables

Job ID: 201811-127019

Job Function
Technical R&D

Schedule
Full time

Location
United States of America - California
South San Francisco

Job type
Regular

Company/Division
Pharmaceuticals

Job Level
Individual contributor

The Position

The Position

The Analytical Operations department prides itself on expertise and leadership in the area of process related impurities as well as high throughput analytical testing and data management to support process development and validation activities. We have an exciting opportunity for a talented scientist to join our team.

The position is focused on evaluating protein-based drug product for leachables, and characterizing extractables from a range of container systems and process equipment. The work will involve designing methods to characterize and quantitate extractables and leachables, collecting and interpreting data for a wide variety of protein-based therapeutics, and thoroughly documenting results. A successful candidate will be capable of applying advanced GC-MS and LC-MS methods to evaluate small molecule and impurities in complex solutions. Direct experience applying these analytical methods to impurities or leachables analyses is required. The ability to become proficient in other methods, such as ICP-MS, is important.

This job requires the strong organizational skills and the capacity to manage multiple simultaneous projects. The ability to plan, schedule, and track work for internal and external teams is essential. Documentation of results and authoring of protocols and summary reports are part of the position, so excellent written communication abilities are needed.

Key Job Functions

- Plan and execute testing of protein-based drug product for small molecule leachable content.
- Evaluate in-house extractables data from container systems and process equipment.
- Review leachables data from contract research organizations.
- Review extractables data from vendors and other external sources.
- Provide SME knowledge in the areas of GC-MS and LC-MS.

- Help support other analytical methods, such as ICP-MS.
- Troubleshoot instruments and methods.
- Communicate results to project teams and advise on the proper experimental design for E&L testing.
- Author protocols, summary reports, and regulatory submissions.

Who You Are

- Ph.D in Chemistry, Biochemistry, or related scientific field, or equivalent combination of Bachelor's/Master's and experience.
- 5+ years of experience and an advanced knowledge of small molecule LC-MS and GC-MS.
- Experience with extractables and leachables as related to primary container closure and process equipment.
- Strong organizational skills.
- The ability to work well with a variety of project teams.
- A successful track record of written communication.

#LI-PTD-JM

Who We Are

A member of the Roche Group, Genentech has been at the forefront of the biotechnology industry for more than 40 years, using human genetic information to develop novel medicines for serious and life-threatening diseases. Genentech has multiple therapies on the market for cancer & other serious illnesses. Please take this opportunity to learn about Genentech where we believe that our employees are our most important asset & are dedicated to remaining a great place to work.

Genentech is an equal opportunity employer & prohibits unlawful discrimination based on race, color, religion, gender, sexual orientation, gender identity/expression, national origin/ancestry, age, disability, marital & veteran status. For more information about equal employment opportunity, visit our Genentech Careers page.