

Sr. Associate 2

Job ID: 00410377

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

Job Title: Senior Specialist (E4/5)

Department: PTQBQ Stability

Job Responsibilities:

- Key contributor for developing consistent strategies for stability studies performed at different sites, CMOs and partners
- Manage and monitor milestones and detail timelines for assigned commercial products to ensure the achievement of corporate goals and objectives while providing timely and transparent communication to the PMT subteams and other cross-functional teams.
- Provide scientific rationale for stability study design and propose changes for the Genentech Quality organization
- Provide scientific and technical leadership in Inspection/ Audit situations, thinking

critically and acting creatively while providing information quickly and accurately

- Author and provide scientific as well as technical representation of Stability in all stability relevant sections for Submissions, Regulatory Agency responses, APRs and ARs
- Work closely with other Senior Specialists and senior management to develop strategy for long range operational and resource planning
- Serve as a subject matter expert (SME) for stability questions related to assigned commercial products

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.
 - Strong scientific background in protein chemistry, analytical methods and/or formulation
 - Strong experience in the assessment of technical data is required
 - Strong knowledge of Quality systems
 - Strong leadership and communication skills; strong decision making skills; ability to communicate ideas, opinions and counter arguments in a proactive and professional manner
 - Ability to manage multiple priorities within a fast-paced environment in a positive and collaborative manner is necessary
 - Solid understanding of QA and QC cGMP requirements
 - Ability to work with inter-disciplinary teams in collaborative cross-functional settings
 - Demonstrated commitment and self-motivation

Genentech is an Equal Opportunity Employer.