

Senior Clinical Quality Product Leader / Sr. QC Scientist

Job ID: 00413804

Job Function

Quality Control

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 Product Quality – Biologics group is part of IMP QA. The department is responsible for the product quality for biologics and antibody-drug-conjugates in the global Roche network throughout the development lifecycle to commercialization. As a member of the IMP Product Quality group, the Sr. Quality Product Leader serves as the single point of contact on the technical development teams and is accountable for driving the quality activities for the teams. This position must effectively communicate timelines and issues to Quality to ensure successful manufacturing, product testing/release and regulatory filings. Additionally the position must partner with other organizations throughout Roche Global Pharma Technical Operations, including but not limited to: QA Operations, Commercial Quality, External Quality, Pharma Technical Development (PTD), and Regulatory (PTR). This position will primarily support project activities during late stage development and the process handover from development to commercial as part of new product commercialization.

Responsibilities

- Participate in regular technical development team meetings and provide clear and timely feedback to the teams.
- Communicate timelines and issues to all relevant Quality departments in a timely manner.
- Engage and collaborate with partner groups (e.g., within and outside Quality, external partners, etc.) and across global sites in the Roche network to ensure production, testing and release, and regulatory submission timelines are achieved without compromising product

quality.

- Proactively work with technical development teams, commercial counterparts, and senior management to identify and escalate project quality risks with the goal of delivering a robust process appropriate for commercial filing acceptable to Health Authorities and provides reliable products after launch
- Provide high level oversight of PC/PV, method validation and transfer activities during commercial filing preparation, and ensure timely escalation of timeline bottlenecks to senior management
- Lead Quality investigations, including developing proposals for resolution of product-impacting Quality issues and presentation for endorsement to Quality Review Boards, and oversight of outcome of appropriate CAPA's associated with product-impacting investigations.

Who You Are

- Knowledge of biotechnology/pharmaceutical industry, especially within the areas of pharmaceutical development, manufacturing, process development, analytical sciences and/or Quality. Familiarity with device development and drug conjugation chemistry are a plus.
- Previous membership on or direct interactions with technical development teams required. Must be capable of working in a team environment and collaborating with colleagues within department and other functional areas to achieve goals.
- Strong communication skills are required. The candidate must communicate effectively and efficiently at different levels of the organization and at meetings. Successful candidates will be capable of influencing and facilitating groups with diverse perspectives.
- Direct experience with late stage drug development or demonstrated capability of ensuring effective hand-off of robust manufacturing process from development to commercial as part of new product commercialization is required. Experience with pre-approval inspection preparation/support is highly desired.
- Experience with authoring global regulatory submissions (IND, IMPD, CTA, and BLA/MAA), and addressing Health Authority questions on regulatory submissions is required.
- Previous experience as owner or SME for Quality investigations is desired
- Familiarity with (e.g. FDA, EMA, PMDA) regulatory requirements and guidances, and compendia (USP, EP, JP)
- The candidate must have strong ownership of assigned projects and follow through on issues until resolution. Work independently using a high degree of scientific judgment to create solutions by applying a breadth of knowledge and previous working experience. Be able to make prompt decisions based on sound and factual data, plan and prioritize workload, and be able to multitask.
- PhD degree in biological sciences, chemistry or engineering or other related fields with at least 8 years of industry experience; or BS/MS degree with at least 12 years industry experience.

Genentech is an Equal Opportunity Employer.