

Quality Product Leader for Clinical Trial Support

Job ID: 00413390

Job Function

Quality Assurance

Schedule

Full-time

Location

United States-
United States

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 Quality Product Leader is part of Clinical (IMP) QA. This position will be responsible for managing the quality logistics for commercial product used in clinical trials across the network. The job responsibilities include creating and implementing business processes to effectively manage the logistics for small and large molecule active, placebo, and comparators; both product produced by Roche and by a competitor. The position is global. This position will establish and maintain strong partnerships with internal and external colleagues, customers, and stake-holders. These groups are located globally and are comprised of, but not limited to, QA Operations, Commercial Product Quality Stewards, External and Site Quality, Commercial QC, Product Development, Global Supply Chain, Country Qualified Persons and Pharma Technical Regulatory (PTR).

Who You Are

Job Responsibilities

- Manage programs of a global nature and overall supply chain (from supplier/manufacturer of the materials to shipment to clinical site/patients)
- Manage quality activities as needed to support the supply chain, e.g. Product Specification File, Product Specific Requirements for Intra-company Quality Agreements, ensure compliance with Regulatory Submissions, change control

activities, etc.

- Notify Senior Management of significant quality or regulatory issues that may impact product quality or regulatory compliance
- Participate/Lead quality investigation to resolve quality issues; independently present to review committees
- Partner with key stakeholders in Life Cycle Team, Pharma Technical Regulatory, Global Supply Chain, Clinical and Commercial Quality to ensure continued high quality supply of product to patients
- In the absence of a Technical Development Team, develop an information clearinghouse and serve as a SPOC for quality questions
- Participate in the implementation of objectives and long range goals of the IMP Product Quality department
- Maintain a technical proficiency in pharmaceutical manufacturing, control systems, Health Authority expectations for IMPs and general cGMP compliance

Job Requirements

- PhD degree in Chemistry/Biology, or relevant scientific/engineering discipline or other related fields with 5-10 years of industry experience; or MS degree with at least 10 years industry experience.
- Minimum of 5 years of relevant QA/QC experience in the pharmaceutical industry. clinical quality experience is required, additional commercial quality experience and knowledge of Quality systems for a global organization are a plus
- Demonstrated in-depth knowledge of cGMPs, Health Authority guidances and expectations, United States Pharmacopeia (USP), European Pharmacopeia (EP), strategies for Quality Control testing, GMP facility requirements, and manufacturing operational practices.
- Experience in one or more of the following areas is a plus: change control, investigations, product complaints, lot release, QC testing, GMP audits, Regulatory Submissions.
- Demonstrated strong oral and written communication skills

Approximately 20%-30% travel

Genentech is an Equal Opportunity Employer.