

Head of Biologics External Quality

Job ID: 00414061

Job Function

Quality

Schedule

Full-time

Location

United States-California
South San Francisco

Job type

Regular Employee

Company/Division

Pharmaceutical

Job Level

Executive (Director/VP/SVP)

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

Purpose:

Accountable for the deployment and realization of the Quality and Compliance strategy for PharmaGlobal Technical Operations (PT) External Quality Operations CMO - Biologics.

Key Responsibilities:

- Direct accountability for Quality and Compliance activities and organization across PT's external CMOs for Biologics
- Leading deployment and full realization of the PT Quality System requirements through Quality Agreements and Contract Quality Requirements with external CMOs.
- Ensure an objective, proactive cGMP compliance program is established and operational.
- Quality responsibility for extension of manufacturing network into EM (India, Russia, Brazil) and for Devices
- Product quality management activities
- End-to-end external CMO - wide Quality Risk management
- Direct continuous improvement activities of external CMOs to improve Quality and Compliance performance.

- Sponsor for the Global Quality external CMO issues management process and system.
- Directly responsible for External Quality Operations CMO organization
- Overall budget and financial performance for External Quality Operations CMO organization.
- Accountable for demonstrating and realizing Roche's core values and expected behaviors.

Who You Are

- Experience in multiple technical Drug Product platforms (bulk drug substance, sterile, devices and combination drug products) and product life cycle
- 5 to 10 years operational experience as PT site head/QSH
- Experience with working in matrix organizations
- Solid Quality Business Acumen
- At least 15 years industry experience in pharma/biopharma business
- Strong communication, collaboration skills
- Strong interpersonal skills with proven high level influencing and negotiation skills
- Excellent verbal and written communication skills
- Excellent at building and maintaining constructive and effective relationships with internal and external stakeholders
- Strong collaboration and team building skills across cultures, countries, technical competences, and organizational levels.
- Capability to manage complex situations
- Ability to deal with concepts, ambiguity and complexity skillfully and comfortably
- Manages 3 to 5 direct reports. Total reporting in Bio: 80
- Ability to lead cross-site and network wide activities without direct line responsibility
- Strong quality and compliance understanding
- Strategic agility

Genentech is an Equal Opportunity Employer.