

GNE Principal Compliance Specialist

Job ID: 00414074

Job Function

GMP Compliance

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

3 positions available for locations in SSF. Washington DC or Basel

Main Purpose of the Position:

- Provides objective and uniform assessments of quality and compliance risks across global network, including independent expert review of (1) the internal GMP auditing program and (2) correspondence to global health authorities regarding GMP issues.
- Supports support liaisons and interactions with external bodies and committees to influence on technical quality issues through articles, speeches and participation on committees

Job Duties/Responsibilities:

- Performs independent expert assessment to determine global uniformity and conformance to appropriate regulatory standards for (1) internal GMP audits and (2) correspondence to global health authorities regarding GMP issues, including written

responses to inspectional observations.

- Advise senior management across PT Global network on best practices, regulatory intelligence, key opportunities, and possible threats in the areas of quality and compliance.
- Provides up to date regulatory and compliance information and trends, specializing in specific regulatory authorities and regions, providing timely information to the PTQ organization.
- Contributes to expert GMP compliance opinions for PT Global network, including Manufacturing, Quality, and Regulatory Affairs.
- Participates as a key member of teams throughout the global Technical Operations Quality organization for strategy and policy, external interactions and influencing activities as they relate to Quality and GMP/GDP Compliance
- Supports the overall efforts for strong health authority relationships in the areas of Quality and Compliance through effective communications, interactions and participation in meetings, conferences and committees with focus on respective region or area of expertise.

Who You Are

Qualifications: Education, Experience, Knowledge and Skills:

(Minimum requirements)

- Education: Bachelor (preferably in life science) degree required; pharmacy degree or advanced degree in scientific, technical, legal or regulatory area preferred
- Experience: 15+ Years or 13+ Years with Masters or 10+ Years with PhD / JD with emphasis on quality, regulatory and compliance-related manufacturing issues. Previous experience working inside a regulatory agency is preferred.
- Expert in the area of Quality and Compliance including primarily GMP/GDP and also CMC issues; previous experience working inside a regulatory agency is preferred.
- Experience with manufacturing, compliance and regulatory issues including knowledge of quality systems, quality risk management and their relationship to manufacturing
- Interaction with industry and professional organizations in manufacturing quality areas to include participation or leading workgroups and giving presentations
- Strong people skills and related attributes, including initiative, flexibility, accountability and the ability to collaborate across cross-functional teams
- Proven ability to be part of a team responsible for the execution of successful innovative GMP and CMC regulatory strategies in the areas of Quality and Compliance
- Excellent communication skills, both oral and written.
- Proven ability to communicate and interact with global health authorities
- Ability to travel approximately 10%

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