

Quality Manager

Job ID: 00414103

Job Function

Clinical Operations

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

Here is an opportunity to join Roche as a Quality Manager. This position is responsible for proactively ensuring that all GCP governed clinical activities within the department (PDG – Operations) are delivered to the highest standards of quality and efficiency in accordance with the appropriate Roche and industry requirements and regulations.

The Quality Manager promotes quality and compliance excellence within PDG Operations by embedding quality principles throughout the organization. This is achieved through:

- Close collaboration/partnership with the Product Development operational staff
- Facilitation of subject matter experts within and outside PDG
- Close liaison with PDQ (global quality group)

Main Responsibilities:

Quality Management System (QMS) – You will be required to understand and maintain the QMS requirements for the business and develop and implement the QMS and monitor its performance.

Ensure cross functional alignment and compliance through process documents - By analyzing/reviewing "to be" processed, forms, templates and related process documents and facilitate review and approval of process documents along with global and cross functional teams. The Quality Manager will coordinate the functional subject matter experts

by scheduling review and implementation of new/revised process documents.

Risk management strategy - Ensure strategic quality risk management activities are implemented and maintained and enable identification of key risks for escalation to study teams and senior management.

Performance metrics - Develop and implement the most appropriate key performance indicators (KPIs) for the business and monitor their effectiveness and gather and report on the metrics which give performance data on the chosen KPIs.

Compliance support - Provide timely GCP compliance support to personnel by answering questions and providing advice and facilitate escalation of compliance issues through the appropriate routes and with appropriate urgency.

Additional duties include:

- Continuous Improvement
- Training Compliance
- Facilitation of simple aligned business processes
- Inspection Readiness and supporting Sponsor inspections
- Records compliance

Who You Are

Who you are: You are educated to a University degree or equivalent in medical/pharmaceutical/scientific/healthcare discipline with strong experience in a quality role in the pharmaceutical industry.

To be successful in this role, a solid knowledge of GCP and awareness/understanding of the global regulatory landscape will be required, along with proven ability to influence people at different levels within a matrix organization.

You will have an understanding of quality management as applied in clinical research and hold the ability to work closely with operations staff, ensuring practicality of quality management processes and proposals.

Excellent communication skills via all methods i.e. face to face, phone, email, teleconference, video conference is essential as is the ability to prioritize and organize a high volume and varied workload while ensuring a high level of attention to detail, accuracy and compliance with deadlines.

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