

Sr. Quality Manager

Job ID: 00414105

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

The Senior Quality Manager is responsible for proactively ensuring that all GCP governed clinical activities in PDG (Product Development Operations) are delivered to the highest standards of quality and efficiency in accordance with the appropriate Roche and industry requirements and regulations.

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

- Close collaboration/partnership with the PD Operational staff
- Facilitation of subject matter experts within and outside PDG
- Strategic liaison with PDQ (global quality group)
- Staying abreast of internal and external developments, trends and other dynamics relevant to the quality and efficiency of PDG

Main duties and responsibilities:

Quality Management System - Analyze and drive the QMS requirements for PDG and Implement, review and manage the QMS and monitor its performance.

Ensure cross functional alignment and compliance through process documents - Analyze/review "to be" processes, forms, templates and related process documents.

Coordinate the functional subject matter experts by scheduling review and implementation of new/revised process documents and develop and maintain effective relationships with other departments to ensure that all controlled document review activities are executed efficiently and effectively.

Risk management strategy - Implement, review and maintain strategic quality risk management activities and implement, review and maintain systems that enable identification of key risks for escalation to study teams and senior management.

Performance metrics - Implement, review and report the most appropriate key performance indicators (KPIs) for the business and monitor their effectiveness Implement, review and maintain processes that enable oversight for PDG management and personnel on the metrics which give performance data on the chosen KPIs.

Compliance support - Drive the compliance support process for PDG in order to create a compliant workforce and workplace based on Regulator's requirements. Provide timely GCP and process compliance support to personnel by answering questions and providing advice manage the process for escalation of compliance issues through the appropriate routes and with appropriate urgency.

Additional duties and responsibilities:

- Continuous Improvement
- Training Compliance
- Facilitating simple aligned business processes
- Inspection Readiness and supporting Sponsor inspections
- Lead and/or supervise other key projects as required

Who You Are

Who you are:

You are educated to degree level in medical/pharmaceutical/scientific/healthcare discipline with extensive experience in a quality role in the pharmaceutical industry – You hold expert knowledge of GCP and have the ability to interpret the global regulatory landscape and implement any requirements within the global environment.

To be successful in this role you will have experience in influencing people at different levels within a matrix organization and understanding how to prioritize and organize a high volume and varied workload while ensuring a high level of attention to detail, accuracy and compliance with deadlines.

You are highly self-motivated and organized; able to lead initiatives with authority, creativity and innovative methods and are proficient in Microsoft Word, Excel, PowerPoint, Visio and Project .

You will demonstrate comprehensive understanding of quality management as applied in clinical research and work closely with operations staff, ensuring practicality of quality management processes and proposals.

Professional and Technical Requirements:

- University degree or equivalent
- Minimum of 5 years' experience in a quality role in the pharmaceutical industry

- Ability to apply knowledge and experience practically to complex situations
- Computer literacy
- Excellent communication skills via all methods i.e. face to face, phone, email, teleconference, video conference.
- Ability to listen, interpret and summarize information; provide clear, concise verbal communication; provide professional and concise written communications
- Ability to manage others within a project/work stream in order to achieve an objective

Technical Competencies:

1. Strong communication skills in a multicultural environment.
2. Proven ability to influence others and experience as a project leader.
3. Attention to detail and high level of accuracy in work delivered.
4. Creative and innovative.
5. High level of initiative and ability to function independently with minimal supervision.

Other:

National/international travel may be required and may be outside of business hours. Time zone differences in global communications will require regular teleconferences outside of standard working hours.

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