

GCP Strategy Lead Therapeutic Support (Oncology)

Job ID: 00409467

Job Function

Clinical Audit

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

Job Purpose:

The PDQA GCP TA Strategy Lead is responsible for the development and implementation of a GCP risk based strategy to deliver an audit program and quality oversight model for studies/products within a therapeutic area. This role provides oversight to the PDQA program contacts to ensure consistent application of risk based strategy for each program within a TA, and provide actionable data to Therapeutic Area Senior PD management based on analysis of data (audit/inspection/risk) and identification of trends. This role is to influence TAs in the area of risk and quality management so they can proactively identify and address issues.

Primary Responsibilities and Accountabilities:

- Design and implement a global GCP risk-based Strategy for audit and risk assessment activities for each program in a TA
 - Develops and performs risk assessment strategy on each program in TA
 - Supports Program Contacts in risk assessment for each study in program and helps define PDQA priority studies list

- Develop and maintain risk assessment tools
- Monitors risk data and recommends risk mitigation strategies to TA
- Oversee completion of TA and protocol specific Quality plans
- Input program specific information into risk assessments of internal processes and service providers
- Provide back-up support to all Program Contacts for a specific TA
- Assess and adjust the audit strategy for CTC audits (internal and compliance audits)
- Functions as an audit report reviewer for outsourced CTC Compliance audits
- Analyze data/metrics from audits, inspections and risk management activities for compliance trends and risks for all programs within a specific TA
- Develop and deliver summary reports (audit/inspection/risk metrics and trends) to TA Leadership
- Provide compliance advice to the TA/product teams and PDQA staff
- May lead or participate in GCP audits for TA
- Support inspection readiness and inspection management activities for products within a TA
- Support regulatory authority GCP inspections for products in Therapeutic Area
- Provides leadership and direction to PDQ/PDQA and our customers/stakeholders on GCP related activities/issues
 - Establish strong partnership/relationship with TA Senior PD Management
 - Review and provide feedback on study risk mitigation plans/CAPAs
 - Escalate significant compliance issues to PDQA Management
 - Support PDQ Partner Services in the implementation and oversight of QMS for PDG
 - Provide responses to GCP questions received from Compliance Help Desk for TA
- Contribute to the development and execution of PDQA goals and initiatives
 - Participate in or lead departmental or cross-functional compliance projects and initiatives as assigned
 - Assists and/or contributes to the development and/or revision of PDQA SOPs, guidelines and tools
- Maintains highest level of awareness, expertise in international GCP regulations and internal policies and SOPs

Who You Are

Education/Qualifications:

- Bachelor's degree or equivalent in scientific or quality-related field or equivalent combination of education, training and experience
- Advanced degree in referenced fields preferred

Minimum:

- Minimum 7 years in pharmaceutical industry and/or quality assurance
- Minimum 5 years in Good Clinical Practice (GCP) related discipline
- Demonstrated knowledge of GCP, pharmacovigilance / drug safety and regulatory requirements, as well as analytical, organizational and planning skills

- Project management experience with proven leadership, mentoring and coaching

Desired:

- Proficiency in the conduct of GCP related audits
- Experience supporting GCP regulatory authority inspections
- Experience supporting any of the following therapeutic areas: Oncology, Immunology, Infectious Disease and Ophthalmology.

Experience, Skills, Knowledge:

- Demonstrated ability to effectively communicate, influence and lead both with and without authority.
- Highly effective teamwork and collaboration skills.
- Global team leadership.
- Proven project management skills and able to lead multiple teams
- Demonstrated analytical, problem solving and decision-making skills
- Proven demonstration of leadership, strategic and system thinking
- Ability to work effectively in an international multicultural matrix organization.
- Effective communication and customer management skills.
- Fluency in written and spoken English
- Demonstrated knowledge of product development related global regulatory requirements

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