

Sr Manager QA (Service Provider Strategist)

Job ID: 00412326

Job Function

Development

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

We are recruiting for the position of Service Provider Strategy Lead to join our international Product Development Quality Assurance (PDQA) team.

Reporting to the Team Lead for Service Provider QA Strategy the ideal candidate will be responsible for the design and implementation of the Service Provider risk management and audit strategy across the GLP, GCP, GPVP areas. The role works in partnership with Procurement/Outsourcing Functions and the PDQA GLP, GCP, PV Strategy Leads to ensure that Risk Assessments are maintained across the inventory of Service Providers engaged globally (gRED, pRED, PD, GPS/gMED) and at Affiliate Level.

This role monitors activities outsourced to Service Providers through periodic risk assessment, risk-based routine audits and provides ongoing support to mitigating actions. It also provides actionable data to Senior Procurement/Outsourcing functional management based on analysis of data (audit/inspection/risk) and identification of trends.

The ability to influence business partners in the area of service provider risk and quality

management is essential to proactively identify and address issues with the skill to ensure that service provider quality issues are addressed in a timely manner and that the relevant management functions in the organizations are kept informed.

Key responsibilities and tasks:

- Design and implement the PDQA Service Provider risk-based strategy for risk management and audit activities
- Define/maintain the “audit/risk universe” of Service Providers based on input from Procurement/Outsourcing functions and PDQA GxP Strategy Leads
- Partner closely with the GxP Strategy Leads, Procurement/Outsourcing Functions to ensure that risk assessments are maintained for Service Providers to determine which audits will be conducted and where risk mitigation activities should occur.
- Develop and implement a GxP risk based strategy to deliver an audit program and quality oversight model for service providers within service category areas.
- Assess specific risk areas on an on-going basis, communicate to PDQA senior leadership and propose modifications to PDQA strategy where necessary
- Develop and maintain risk assessment tools
- Assess data/metrics from audits, inspections and risk management activities for compliance trends and risks
- Develop communication tools (reports/dashboards) for audit and inspection metrics and trends
- Escalate significant compliance issues to PDQA Management
- Represent QA on Service Provider sourcing initiatives and Strategic Alliance or Category governance teams, participating in Service Provider due diligence visits where appropriate.
- Support regulatory authority GCP inspections at service providers.
- May lead or participate in GCP audits at service providers
- Provide leadership and direction to PDQ/PDQA and our customers/stakeholders on GxP related activities/issues related to Service Providers
- Establish strong partnership/relationship with key stakeholders in Procurement and Outsourcing functions
- Review and provide feedback on service category area risk mitigation plans/CAPAs
- Provide quality leadership on complex issues (i.e., CHD) to Procurement/Outsourcing functions and PDQA staff
- Represent QA on Service Provider Strategic Alliance or Category Governance teams.
- 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 knowledge of GLP, GCP, PV regulations and internal policies and SOPs
- Maintains highest level of awareness and expertise in international GxP/PV regulatory requirements, guidelines, and policies, and applicable Roche/Service provider SOPs and project-specific procedures.

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 experience:

- Extensive experience in the pharmaceutical industry and/or quality assurance with excellence knowledge of Good Clinical Practice (GCP) or Pharmacovigilance (PV) Service Provider Quality role
- Demonstrated knowledge of GLP, GCP, CSV, Pharmacovigilance (PV) / drug safety and regulatory requirements.
- Project management experience with proven leadership, mentoring and coaching skills.

Desired:

- Experience supporting Service Provider sourcing initiatives and/or representing QA on Service Provider Strategic Alliance or Category governance teams.
- Proficiency in the conduct of GxP related audits of Service Providers.
- Experience supporting regulatory authority inspections.
- Experience overseeing one or more of the following categories/technologies: Data Capturing, Endpoint Adjudication, Imaging, IxRS, Reported Outcomes, Rating Instruments.

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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