

Senior Audit & Inspection Management

Job ID: 00407649

Job Function

Information Technology

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

IT Quality is a trusted partner for customers to ensure and improve the overall quality of IT systems throughout their lifecycle with a focus on compliance with regulatory, legal and finance requirements. We are looking for a customer-focused, highly collaborative individual responsible hosting and supporting audits and inspections and ensuring audit corrective actions are tracked and closed in a timely manner. The position is responsible for effective planning and management of audits and inspections with business quality and audit groups. Further responsibilities include:

- Leads, hosts, and supports audit management for IT for various sites for internal and external audits and inspections and provides regular updates to stakeholders and informs management of potential issues
- Prepares IT teams for audits and inspections using his/her knowledge of IT controls and auditing practices and provides training to IT staff in support of key IT controls and audit readiness procedures
- Manages the audit program in compliance with quality requirements for ICFR, FDA regulations, legal and security policies, IT controls.
- Facilitates execution of corrective actions ensuring that weaknesses identified in the IT management system are identified, recorded, prioritized and addressed appropriately.
- Conducts vendor audits and internal system assessments for Informatics
- Serves as custodian for legacy IT controls, IT Narratives, Master Audit Schedule to

- support audit and compliance processes.
- Develops, monitors and improves processes and tools to improve the compliance of IT systems and to facilitate joint business decision making from a cross-functional and global perspective
- Develops strong working relationships with and partners effectively with IT delivery teams and with global Business Quality, Corporate Audit, Finance and security organizations
- Maintains industry knowledge and skills in the compliance, audit, and risk management and applies them to improve internal processes and practices

Who You Are

- 5-9 years of professional IT experience in a major, global organization and leading teams
- Experience working in a regulated environment and with internal controls related to financial and regulatory policies, quality assurance, risk management on a global scale
- Knowledge of GxP, health authority regulations, systems financial controls, software development lifecycle, computer systems validation, infrastructure qualification, and ITIL processes
- Customer service and process focused
- Strong project management and analytical skills
- Strong written and verbal communication and collaboration skills
- Ability to travel as required up to 25% - Advanced English reading, writing, speaking and listening skills

Genentech is an Equal Opportunity Employer.