

GCP Inspection Specialist

Job ID: 00371548

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

GCP experience required for consideration

Position Purpose

The Inspection Specialist supports the Roche/Genentech Pharma and gRED/pRED organizations by coordinating, managing, and preparing for Good Clinical Practice (GCP), Pharmacovigilance (PV), and Investigator Site inspections conducted by global health authorities.

Major Responsibilities and Accountabilities

- Coordinates scheduling and logistics for inspection related activities.
- Collaborates with other Pharma / gRED / pRED functional areas for activities related to inspection preparation. Activities include, but are not limited to, preparation of relevant materials and conducting inspection related training.
- Participates in pre-inspection visits of investigator sites (approximately 20% travel).
- Participates in health authority inspections and helps ensure that roles and responsibilities have been defined and assigned for each inspection. Assumes a role

- as required by the scope and nature of the inspection.
- Provides guidance to inspected parties regarding the completion of inspection corrective and preventative action plans (CAPAs).
 - Assists in the preparation, conduct and management of mock inspections conducted of Roche/Genentech functional areas.
 - Assists in developing and maintaining policies, standard operating procedures (SOPs), and guidelines for preparation and conduct of inspections within Roche/Genentech Pharma.
 - Assists in preparing periodic summary reports and trend reports related to Roche/Genentech inspections.
 - Develops and maintains expertise in international GCP regulatory requirements, international PV regulatory requirements, and policies, SOPs and project-specific procedures within Pharma applicable to the clinical trial methodology and Pharmacovigilance processes.
 - Monitors trends in health authority inspection activities to proactively identify potential areas of risk for Roche/Genentech.
 - Responsible for the coordination of Inspection Readiness (IR) modules and if required provides a country-specific / function-specific summary report.
 - Provides support to the IR Program Manager.
 - Provides support to and communicates with Inspection Readiness Key Contact (IRKC) personnel globally.
 - Assists in identifying needs for updates to training materials, IR modules and all documents required for the IR program.

Who You Are

Minimum of a Bachelor's degree in a scientific or health-related field with at least 5 years of relevant industry experience

Minimum of 2 years in quality assurance/compliance required with a working knowledge of GCP and PV regulations. Prior auditing and/or or health authority inspection experience highly desired.

Experience and/or Competencies Required

- General computer proficiency (e.g., Microsoft Office Suite applications).
- Proven project management skills
- Ability to work both independently and in a team environment
- Strong communication skills; verbal and written
- Critical thinking and decision-making skills
- Detail-oriented with the ability to prioritize, organize, plan and manage multiple tasks efficiently
- Prior participation in GCP and/or PV inspections is desirable

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