

Clinical Safety Associate I

Job ID: 00412885

Job Function

Medical Information

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

Summary of Position:

The Clinical Safety Associate I (CSA I) assists in the clinical processing of adverse event (AE) information received by US Pharmacovigilance (USPV). Responsibilities are performed under the direction of the USPV Manager.

Job Duties/Responsibilities:

- Demonstrated knowledge of safety concepts, per ICH and FDA guidelines per drug safety reporting requirements.
- Performs a review of ancillary documentation accompanying ICSR reports and identifies pertinent clinical information for incorporation into the case narrative.
- Performs Data Capture and Quality Review for all molecules and serves as a back up for additional projects.
- Identifies and initiates requests for case follow up for clinical trials and post marketing adverse events.

- Works with Submissions Team Responsible to properly identify US regulatory reporting requirements.
- Demonstrates a general understanding of appropriate labeling documents for assigned project(s).
- Demonstrates knowledge and understanding of safety exchange agreements (if applicable).
- Participates on Study Management Teams (as applicable)
- Assists in the development of drug safety presentation for investigator meeting presentations.
- Assists in clinical trial reconciliation process (as applicable).
- Organizes work load to ensure compliance with regulatory timelines for ICSR reporting.
- Ensures departmental workflow processes and timelines are followed.

Competencies Identified for Success:

- Works effectively as a team member and promotes collaboration
- Demonstrates initiative and accountability
- Strong organizational skills, detail oriented, ability to adapt to change
- Confident decision maker

Who You Are

Education, Experience, and Other Requirements:

- RN, BSN, PA, NP, MSN, MD, or PharmD required
- Minimum 2 years of clinical experience in a health care related field
- Computer proficiency and data entry experience preferred
- Excellent communication skills, both written and verbal
- Previous experience in Drug Safety (preferred)

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