

Sr Compliance & Training Manager

Job ID: 00411418

Job Function

Drug Safety

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 Compliance & Training associate reports directly to the Manager, Compliance & Training. This individual will work closely with the US Drug Safety staff to support all safety-related activities accountable to US Drug Safety. In addition, interactions US Medical Affairs Compliance will also occur on an as-needed basis.

Job Duties/Responsibilities:

- Training of vendors and other 3rd parties to drug safety reporting requirements
- Working with commercial organization to ensure monitoring of Genentech sponsored websites for adverse event reporting
- Oversight of US Drug Safety audit and inspection findings and CAPAs
- Oversight of US Drug Safety local procedures and controlled documents
- Management of US Pharmacovigilance & Safety Data Exchange agreements
- Management of US Drug Safety global pharmacovigilance commitments
- Monitor IT issues
- Management of special projects
- Track US pharmacovigilance metrics
- Conduct vendor assessments for AE reporting compliance

- Interact, where applicable, with US Medical Affairs Compliance to address safety-related issues or concerns

Who You Are

Competencies Identified for Success:

- Demonstrates strong, dynamic leadership.
- Effective team player encouraging collaboration within and across functional areas.
- Sound strategic evaluation, analysis, and decision-making skills
- Able to handle pressure in a dynamic, fast paced environment.
- Effectively formulates strategies, tactics and action plans to achieve results.

Education, Experience, and Other Requirements:

- Bachelor's degree in a health care field with relevant pharmaceutical industry experience in drug safety
- Minimum of 3 years experience in the pharmaceutical industry
- Expert knowledge of FDA safety regulations, ICH Guidelines, and other applicable regulatory guidance documents; working knowledge of global safety regulations.

Genentech is an Equal Opportunity Employer.