

Principal Safety Scientist (NonMD)- Licensing & Early Development

Job ID: 00410500

Job Function

Drug Safety

Schedule

Full-time

Location

United States-California
South San Francisco

Job type

Regular Employee

Company/Division

Pharmaceutical

Job Level

Manager with Direct Reports

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

GENERAL POSITION SUMMARY/PURPOSE:

Roche's PDS organization is structured by product development phases, therapeutic areas and sites. PDS enhances healthcare for patients by understanding and communicating the safety profile of Roche medicines to optimize their benefit-risk profile. Principal Safety Scientists in the Licensing and Early Development (LEAD) group supporting the Genentech Research and Early Development (gRED) organization will be responsible for the oversight of personnel and activities focusing on safety-related operational support of the early development teams within gRED. Principal Safety Scientists will be responsible for both the coordination of these activities and supervision of Clinical Safety Associates (CSA) within the LEAD-gRED group, and for individual contribution to these activities for a portion of the portfolio. The Principal Safety Scientist will report to the Associate Head of LEAD-gRED Safety Science.

Cross-Functional Team Membership

- Ensure appropriate coverage for all Protocol Execution Teams (PET/CPET) or Study Management Teams (SMT) for assigned molecules via supervision of CSAs and via individual contribution where needed. Coordinate and liaise with the LEAD_gRED

Associate Head and the gRED PET Leaders (PETL/CPETL) to ensure coverage of the necessary activities.

- Proactively interface with gRED Protocol Execution Team Leader (PETL) to identify operational support needs for Safety Management Team (SMT) and/or Protocol Execution Team (PET) and prioritize coverage as needed
- Acts as single point of contact for CROs and affiliates with respect to safety operations activities
- Coordinate with PETLs to provide support to CRO regarding scope of work, requests for proposals, safety management plans, and kick-off activities

Product Development Safety-Related Operational Support for gRED early development teams

- Demonstrate advanced knowledge of safety reporting concepts, focused on standards set out in ICH and FDA guidelines for drug safety reporting requirements.
- Assists gRED Clinical Operations with ensuring appropriate inclusion of safety reporting information for investigator and site training; Independently performs clinical trial reconciliation (as applicable).
- Review and address deviations in safety reporting sections of protocols vs protocol template; review and implement protocol specific reporting requirement e.g for Adverse Events of Special Interest; and ensure corresponding database and reporting processes are in place (e.g. IMP designation, appropriate listing of protocol in ARISg).
- Contributes to safety reporting sections of periodic reports (e.g. IND Annual Report, DSUR).
- Provide general assistance and expert input to the LEAD-gRED team members with the PDSS-PDSO interface.

Process

- Demonstrate knowledge of requirements of clinical trial processes including CRO management, investigator and site training needs with respect to safety reporting, and safety data exchange agreements (SDEA).
- Coordinate SDEA process to ensure liaison between PET, PDSO representatives, and DSL members.
- Expected to play an advanced, expert role in PDS's/PDSS's policies, procedures, processes and other infrastructure developments.

Managerial activities

- As needed or otherwise appropriate, assists with recruitment, training, and/or coaching of new or less experienced PDSS staff members.
- Ability to mentor and supervise CSAs.
- Define port-folio responsibilities for CSAs and set clear priorities.

Other

- Stays abreast of internal and external developments, trends and other dynamics relevant to the work of the LEAD-gRED early development safety organization to maintain, at all times, a fully current view and perspective of internal/external influences and/or implications for the assigned activities.
- Maintains the highest standards and levels of knowledge in the specific areas assigned.
- Completes and/or leads other special projects, as and when assigned, or otherwise requested. Expected to contribute to PDS and PDSS beyond the bounds of his/her position and products; including leading and/or participating on cross-functional teams

- and work groups.
- Provides additional support to his/her manager, and others, as needed.
- Consistently complies with all governing laws, regulations, Roche SOPs and other guidelines.

Who You Are

QUALIFICATIONS & EXPERIENCE:

- PhD, PharmD, Pharm, MS or equivalent qualification and clinical competence in the relevant therapeutic area
- Prior industry experience in drug safety is required
- Advanced industry experience in clinical development or medical affairs (4 or more years)
- Advanced knowledge of pharmacovigilance practices and processes
- Advanced knowledge of US and EU pharmacovigilance regulatory requirements
- Advanced knowledge of safety-related operational activities in the early development setting
- Strong management and supervisory experience
- Fluent in English (verbal and written)
- Computer literacy and familiarity with relevant software and systems

ABILITIES:

- Has impeccable ethics. Demonstrates, or proven abilities to demonstrate, Roche Values & Leadership Competencies
- Outstanding attention-to-detail
- Widely respected by others for his/her contribution and competence (whether demonstrable inside Roche or another organization)
- Has advanced knowledge of the pharma/biotech industry, the multiple functions and roles involved in the drug development process.
- Advanced analytical thinking and problem solving skills.
- Proven abilities to prioritize multiple tasks and goals and ensure the timely, thorough and accurate accomplishment of such
- Strong interpersonal, verbal communication and influencing skills: can influence without authority and has proven experience building and cultivating relationships with key partners and stakeholders, both internally and externally
- Outstanding written communication skills
- Strong business presentation skills: effective at summarizing and presenting the key considerations and decision-points
- Confident and competent when interacting with varying levels of internal/external management and others: stays focused and on-point; is able to raise problems or challenges in a productive and mature manner
- Strong negotiation skills: can effectively drive discussions and decisions toward desired end-results
- Proven track record of effective decision-making: makes good business decisions and exercises sound judgment. Consistently and effectively balances decisions with imperatives for ethics and efficacy
- Strong orientation to teamwork
- Ability to travel globally, as necessary

Genentech is an Equal Opportunity Employer.