

Safety Science Leader (MD) - LEAD

Job ID: 00402278

Job Function

Drug Safety

Schedule

Full-time

LocationUnited 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**Job Summary:**

Working in early clinical development at Genentech /Roche Inc gives the opportunity to provide translational safety contribution to projects combining good understanding and knowledge of toxicology and expertise in clinical safety and early clinical development, a very innovative approach where Genentech/Roche is a pioneer.

Job Purpose: The Safety Science Leader (SSL) is accountable for all aspects of safety related to products in early development phase including single case assessment, aggregate reporting, integrated signal prediction/detection (ISP/ISD), integrated risk management process (ISMP) & comparative benefit/risk (in collaboration with Clinical and Regulatory) throughout the life cycle. The Safety Science Leader leads product specific safety analyses including medical evaluation, risk management, signal detection using epidemiology and other input as appropriate to ensure that adequate safety measures are implemented based on data. The Safety Science Leader maintains an Integrated Safety Management Plan (ISMP) throughout the life cycle of the product or medicine and is accountable for safety components of various documents including study protocol, study reports, development study reports. The Safety Science Leader represents Safety Science in Research and Early Development teams (RED teams) . She/ He supports and facilitates transition of projects

from early to confirmatory development for all aspects pertinent to safety.

Primary Responsibilities and Accountabilities:

- Contributes to scientific publications (abstracts, posters, papers) for scientific meetings/journals and approves submissions from a safety perspective.
- Reviews all communications to the public from a safety point of view.
- Keeps the EU QPPV fully informed of any changes to the benefit-risk relationship and, where appropriate, performs tasks as delegated by the EU QPPV.
- With the CSL and the DST, plans and performs, on an ongoing basis, an evaluation of the safety data to detect safety signals. On an ongoing basis with the team, evaluates the Benefit/risk relationship of the program and determines how to manage patients within and across trials.
- Is accountable for safety components of all NDA documents.
- Is responsible for the writing and maintenance of RMP/REMS NDA documents.
- Represents Roche in interactions with Health Authorities and Independent Data Safety Monitoring Boards (ie Pre-BLA/NDA meetings, advisory committees) for safety related topics.
- Contributes to and where specifically delegated may be responsible for the proper execution of the post-approval RMP/REMS
- Ensures that all safety processes are properly supported and compliance is documented for all studies conducted by PD or PB or affiliates.

People Leadership:

- Provides provide leadership and line management to the Safety Sciences department across multiple locations, aligning with other parts of the organization, where necessary.
- Ensures that the performance of direct reports is proactively managed and that they are coached, trained and developed to maximize their contributions.
- Allocates resources and is accountable for the assignment of his/her collaborators / reports according to their individual capabilities and in line with projects priorities.
- Ensures that staff communication and employee relations are managed proactively to maximize the well being of employees.
- Actively installs the Roche values in the Safety Team and their activities.

Who You Are

Education Minimum:

Physician who would be eligible for medical practice in EU or in US

Strongly desired: Post doctorate experience in a specialty such as internal medicine,

pediatrics, or geriatrics is highly valued.

Qualifications:

- Previous experience in the pharmaceutical industry (preferably including safety but may be in clinical development or medical affairs).
- Significant period of time in clinical practice
- Significant experience with drug development including the evaluation and interpretation of scientific and clinical data.
- Demonstrated knowledge of Safety Science across a breadth of therapeutic areas particularly in relation to issue management and signal detection and evaluation.
- Solid knowledge and understanding of US and EU pharmacovigilance regulatory requirements and general regulatory expectations
- Proven experience in proactively leading a team of individuals potentially located across a number of sites and leading them to optimize their performance and contribution.
- Ability to interact with Health Authorities as the primary contact person for safety aspects in face-to-face meetings.
- Ability to travel nationally and internationally.

Genentech is an Equal Opportunity Employer.