

Vice President, Drug Safety Science Oncology Therapeutic Head

Job ID: 00384462

Job Function

Drug Safety

Schedule

Full-time

Location

United States-California
South San Francisco

Job type

Regular Employee

Company/Division

Pharmaceutical

Job Level

Executive (Director/VP/SVP)

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 Purpose:

The Head, Safety Sciences, leads and directs one of the therapeutic areas of safety science aligned with the Oncology disease to provide strategic direction and standardization of performance across the Safety Science groups.

The Head, Safety Sciences directs Product Development Safety's (PDS) disease area specific scientific analysis including medical evaluation, risk assessment and management, signal prediction/detection, Comparative Benefit Risk, using epidemiology and other input as appropriate.

The Head, Safety Sciences will ensure the incorporation of Comparative Benefit-Risk concepts in the disease area strategy and product plans and their use throughout the development and commercial lifecycle of products assigned to the cluster to ensure their longevity. In general, he/she is a member of a Development Review Committee (DRC).

Primary Responsibilities:

- Ensure proactive surveillance and monitoring activities across their safety science cluster to ensure that Roche is aware of potential emerging safety issues and has

developed strategies & action plans to prevent & mitigate risks.

- Direct and manage the SSLs and their teams within the safety science therapeutic area and provide guidance to the relevant development and safety committees as appropriate.
- Maintain managerial oversight of issues and outputs from the therapeutic area Safety Teams address or elevate issues to the PDS Global Head, Drug Safety Committee, Lifecycle Teams, Research and Early Development teams, and various committees.
- Ensure the incorporation of Comparative Benefit-Risk concepts & qualitative/quantitative methods in the Disease Area (in collaboration with Clinical, Regulatory & Medical Affairs) and their use throughout the development and commercial lifecycle to ensure the safety and longevity of all products in their therapeutic area.
- Lead continuous improvement efforts in Safety Science capability and performance together with the other Heads of Safety Science areas. Provide leadership and line management to their reports and other members of the Safety Sciences department across multiple locations.
- Build and leverage Roche and PDS' influence with internal and external entities to create value for Roche.
- Ensure Collaborative and constructive business relationships with major partners where applicable (with particular interest in Chugai). Ensure particular emphasis is placed on communication flow and inter company.
- Contributes as part of the Global Leadership Team to the overall management of the Safety Risk Management Department.
- Partners with Clinical Development organization to facilitate and collaborate towards the development of new oncology products proactively. Build strategic relationships with Clinical Development Oncology to drive innovative trial designs and influence decision-making.

Who You Are

Education/Qualifications:

Minimum:

- MD with a specialty (Internal Medicine, Pediatrics, Geriatrics, or other relevant to the disease area specialty). An additional degree (e.g. PhD, MBA, MSc, MPH) is a plus,
- 5 years clinical practice required
- 3-5 years pharmaceutical/biotech industry clinical drug development experience desired

Experience, Skills, Knowledge

- Significant clinical experience in treating patients and significant experience in pharmaceutical industry (clinical development, drug safety, medical affairs)
- Previous experience at a management level in drug safety, clinical development or medical affairs, including in the evaluation and interpretation of scientific and clinical

- data. Credible knowledge of Safety Science across a breadth of therapeutic areas.
- Demonstrated experience of managing global pharmacovigilance activities, particularly in relation to issue management and signal prediction, detection and evaluation.
 - Solid knowledge and understanding of US and EU pharmacovigilance regulatory requirements and general regulatory expectations
 - Solid knowledge of Asian pharmacovigilance regulatory requirements and general regulatory expectations is a plus
 - Proven experience in managing a team of individuals located across a number of sites and in leading them to optimize their performance and contribution. Proven ability to coach and develop people
 - Strong negotiation skills
 - Strong written and verbal communication skills to a variety of levels and teams. Demonstrated persuasion and influence skills
 - Ability to operate objectively and independently as a leader and as a member of a team, as required
 - Proven ability to manage budget and timelines
 - Ability to interact with high level officials in Health Authorities and other policy makers
 - Willingness to undertake significant travel internationally
 - Ability to work effectively across cultures and in virtual environment

Additional Information:

- The Head, Safety Science Oncology could be a member of the Drug Safety Committee.
- Associate Safety Science Oncology Heads will report into this role from various sites.
- When necessary, the Head of a Safety Science may also be the site Head for all Safety Science staff on the site *LI-PM1

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