Genentech
A Member of the Roche Group

Date: 11/07/19

Safety Science Associate Group Director

Job ID: 201910-131044

Job Function
Drug Safety

Location
South San Francisco
California
United States of America

Schedule
Full time

Job type
Regular

Company/Division
Pharmaceuticals

Job Level

The Position

Job Purpose

The PSS Team Leader (PSS TL) reports to a PSS Group Leader and provides line-leadership for a team of scientists, physicians and/or other health professionals, of varying levels of experience and seniority, who operate in support of complex scientific safety and pharmacovigilance (PV) activities across all Roche assets throughout the lifecycle. Typically, they manage teams based within a geographic region, although the assets and stakeholders they support are global.

The PSS TL brings personal expertise in one or more areas relevant to the scientific, clinical, pharmacovigilance and/or business-related activities of the PSS function. Since the activities performed across PSS are diverse, they must also be adept at identifying and working with wider scientific safety experts: Allowing them to coordinate and support the varied scientific contributions that their teams must deliver, and ensure broad support for the ongoing development needs of their teams (e.g. coaching, training, etc). They will ensure oversight of team performance in terms of delivery quality, and their ability to collaborate effectively with colleagues across the scientific functions and the wider PDS. They ensure their team can maintain appropriate training and skills to deliver effectively, including support for the adoption of new techniques and approaches.

Excellent line-leadership abilities are critical for the TL to succeed. The TL will be responsible for managing and planning the team's resources; recruiting and developing scientists and HCPs at all levels within the function; managing and motivating the team; and ensuring the appropriate balance of expertise and skills are available to meet the current and future demands, by coordinating the team's training and development. They will promote consistent high quality delivery, a growth mindset and a culture of agility across their group. The TL will therefore seek to role model the changes in behaviour and mindset that are necessary for the function to succeed within the business delivery models across PD and Roche. The TL will also work closely with stakeholders from across PDS functions (e.g. EDS,

LMMS and PVSD), taking accountability for ensuring that their PSS team delivers effectively; and can achieve the seamless provision of scientific and PV outputs/deliverables for its Roche customers.

Job Responsibilities

Leadership behaviors

- The Team Leader role models the Roche Values and Leadership Commitments.
- Sets team direction in terms of remit, emphasis, style, behaviors and culture.

- Driving and embedding the agreed organizational models, the necessary mind-sets, and new ways of working. Supporting and empowering staff to do the same.
- Leading self and others to deliver outcomes, and supporting team member's delivery.
- Bringing critical thinking to shape current issues and opportunities into meaningful, deliverable actions
- Anticipating potential issues, risks and opportunities, in the context of the role.
- Focusing on implementing process improvements and adapting the team's ways of working in order to achieve continually improving quality and efficiency.
- Setting team and individual goals and objectives, ensuring alignment with the PDS safety strategy
- Holding PSS members accountable for their behaviours and actions within the operating model so as to encourage the optimal behaviours and mindsets needed for success

Functional oversight, delivery & stakeholder relationship management

- By leading and engaging with PDS strategic projects, contribute to defining and implementing the PSS vision, priorities, and strategy
- Responsible for overseeing the delivery of PV, safety & risk management deliverables following defined, quality bound processes, via their team of HCP/scientists. The deliverables may include (but are not limited to) clinical trial safety support, patient risk management, safety signal management, safety regulatory reporting. The TL may also need to coordinate team member contributions that are delivered in support of molecule safety strategies and related activities (e.g. Filing-related activities; query responses, etc).
- Where responsibility is delegated from a PSS GL; the TL may also be accountable for the review and/or approval of specific safety science and/or PV deliverables, in line with agreed delivery models and/or defined process responsibilities.
- Responsible for ensuring their team implements appropriate mechanisms to ensure that performance oversight of business, quality and scientific service/output delivery quality can be achieved. Supporting the ongoing production of relevant KPIs, as required.
- In coordination with delivery SMEs, and PSS Alliance Management roles, the TL may also have responsibility for implementing effective service provider mechanisms, to enable oversight of routine PV deliverables.
- Responsible for building strong partnerships within PSS, with scientific safety colleagues (i.e. across EDS, LMMS and PVSD), with other PDS functions (e.g. IPV, BMO, PDSO), and other key stakeholders (e.g. GPOs, Scientific Enablement Leaders, IPV Liaison, etc).

Pharmacovigilance delivery quality

- Ensure that via adherence to process delivery requirements; all relevant Health Authority expectations and related Roche quality requirements are met, across all

relevant areas of process execution and molecule/product support.

- Responsible for ensuring the team's ways of working and deliverables are in continual compliance with relevant GxP requirements, and relevant Roche processes and standards and teams are prepared to contribute to audits and inspections in their capacity as scientific and PV delivery experts.

- Drive consistency and continuous improvement across the assigned team.

Resourcing and staff development

- Identify and manage team members' performance and development through proactive planning, effective recruitment and building strong relationships with partners in EDS and LMMS (e.g. line managers, Safety Program Strategy Leaders (SSLs)).
- Identify and manage resource needs at the SSL level, working under the overall guidance from the PSS LT
- Ensure team members are following the PSS learning and development program so as to equip team members with the required pharmacovigilance, scientific, leadership, communication and additional interpersonal skills to provide the required resources to the early and late safety development functions at all levels.
- Provide direct coaching support in relevant areas of expertise, and ensure the availability of wider expertise to support the development and training of the team in wider safety-related disciplines, if required.
- Contribute to knowledge sharing and proactive planning of resource needs across PSS

People leadership

- Provide effective line-leadership for a team of scientists and healthcare professionals, typically within a geographic region.
- Ensure a "high performance team culture", and that the performance of staff is proactively managed. Ensuring they are coached, trained and developed on both leadership, behavioral and technical aspects of their roles, in order to maximize the contributions and impact delivered by their teams.
- Lead by example and create a positive work environment by encouraging mutual respect, innovation and accountability on a functional and project level, both locally and globally.
- Ensure that direct reports are appropriately trained to comply with company standards.
- Conduct ongoing performance management dialogue and complete the required steps of the performance management cycle, performance calibration, talent management and succession planning.
- Complies with employment laws, regulations and company HR policies and procedures.
- Ensures that staff communication and employee relations are managed proactively within the site to maximize the wellbeing of the employees.

Education, Experience, Skills, Knowledge:

- **Minimum Qualifications:** Qualified healthcare professional or Life Sciences graduate.

- **Preferred Qualifications:** A relevant postgraduate qualification (e.g. PHD/MSc in a Life sciences discipline; Medical qualification; PharmD or other post-graduate health professional qualifications; and/or relevant business management qualifications) would be advantageous.

- **Experience & Background:**

- It is essential to demonstrate an understanding of relevant scientific aspects of safety, PV and/or clinical/patient risk management (e.g. via demonstrable knowledge of the application of GVP, GCP & CTR requirements).
- Experience of operating within a clinical pharmaceutical development environment, and/or clinical/healthcare practice, is preferred. Candidates will typically possess more than 5 years of experience within a biopharmaceutical or clinical research organization, bring a broad understanding of the whole drug development process/lifecycle, and are likely to have direct experience of delivering safety-related activities in support of clinical drug development and/or pharmacovigilance.

- Demonstrable people and project/change leadership skills are key (e.g. via prior line- or matrix- leadership roles), including the ability to provide effective coaching to individuals and teams through a combination of listening, curiosity, intuition, self-management and action and the experience of proactively driving a variety of tasks and projects and delegating to a team.
- Knowledge of international drug regulation, including GCP and GVP.
- Demonstrated ability to lead and influence, with and without authority, in a global matrix environment to drive strategic objectives
- Excellent written and verbal communication skills.
- Proven success in creating and sustaining strong relationships with internal business partners across the organization and creating positive partnerships with external bodies.
- Strong negotiation and conflict management skills.

Travel Requirements:

- Expected to travel internationally

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Who We Are

A member of the Roche Group, Genentech has been at the forefront of the biotechnology industry for more than 40 years, using human genetic information to develop novel medicines for serious and life-threatening diseases. Genentech has multiple therapies on the market for cancer & other serious illnesses. Please take this opportunity to learn about Genentech where we believe that our employees are our most important asset & are dedicated to remaining a great place to work.

Genentech is an equal opportunity employer & prohibits unlawful discrimination based on race, color, religion, gender, sexual orientation, gender identity/expression, national origin/ancestry, age, disability, marital & veteran status. For more information about equal employment opportunity, visit our Genentech Careers page.