

Global Regulatory Leader (Oncology)

Job ID: 00413371

Job Function

Clinical Regulatory Affairs

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

Global Regulatory Leader

Accountable for regulatory management of a project(s) and leading a matrix team of regulatory professionals.

Primary Responsibilities and Accountabilities

- Accountable for global regulatory strategy and global regulatory deliverables for a PD project
- Accountable for leading a matrix team of Regulatory Professionals, and for the RAFT deliverables. Responsible for motivating and inspiring RAFT members
- Responsible for holding regular RAFT meetings, in accordance with RAFT guidance.
- Responsible for representing the regulatory function on cross-functional project teams (Lifecycle Teams).
- Responsible for representing the regulatory function on project specific matters to governance bodies
- Accountable for global regulatory Health Authority Interactions
- Accountable for managing decision-making, and conflict resolution surrounding

regulatory issues within the Project Team and RAFT. Responsible for ensuring appropriate escalation to functional management when necessary.

- Accountable for leading the RAFT on a PD project to:
 - deliver strategic regulatory input to the lifecycle management of a project.
 - deliver specific guidance on regulatory issues such as legislation, guidelines, procedures to internal stakeholders (project team, regulatory function, governance bodies)
 - deliver integrated plans relating to regulatory submissions or specific functional projects
 - deliver regulatory submissions, in accordance with project timelines
 - manage successful interactions with regulatory agencies and
 - analyse and landscape the regulatory environment for impact on the project and to brief internal stakeholders, as appropriate
- Responsible for sharing best practices within function to ensure efficiency and consistency across teams.
- Responsible for leading special regulatory projects/global process initiatives, as assigned.
- Responsible for acting as a change agent and role model within PDR by modeling best practices.

Who You Are

Professional and Technical Requirements

- University degree, preferably in a scientific/ technical discipline
- Excellent knowledge of global regulatory processes and proven experience of successful management of regulatory procedures.
- Excellent practical experience of successfully managing global Health Authority interactions.
- Excellent working knowledge of drug discovery, development, manufacturing and marketing.
- Commitment to performance measures of time, cost and quality
- Fluency in written and spoken English.

Experience, Skills and Knowledge

Leadership :

- Takes responsibility to resolve issues objectively.
- Empower individuals to get their job done as experts on the team
- Encourage change, innovation and accountability within the team and function
- Demonstrate capability to obtain win-win situations in a matrix management organization through influence management skills, persuasion and networking.
- Provide strategic input, sets milestones, allocates responsibility and monitor progress towards results.
- Drive Project Teams and RAFT towards meeting regulatory objectives.
- Network with appropriate functions to obtain resources and resolve conflicts.

Technical Competence:

- Possess working knowledge of scientific and regulatory environment in pertinent therapeutic areas or product class.

- Expert understanding of current and historical global regulatory environment and its impact on assigned products.

Teamwork:

- Work effectively to share responsibility as a team member
- Build trust and respect with and among Project Team and RAFT members.
- Seek opportunities to increase morale/ motivate team
- Encourage change, innovation and accountability within the team and function.

Communication:

- Influence individuals or groups at more than one level who may have different interests or goals to reach consensus and achieve team objectives.
- Express complex ideas clearly/succinctly both in writing and verbally.
- Build trust and respect with peers and team members.
- Foster good interpersonal relationships and open communication. Listen and facilitate discussions.
- Skilled at conflict resolution/ negotiation.

Strategic and Innovative Thinking:

- Demonstrate ability to analyze data and regulatory environment, and apply this regulatory and scientific knowledge to determine solutions and solve complex problems. Develop clear, effective and creative regulatory strategies to support goals.
- Demonstrate ability to assess priorities and set strategies to align with/meet business needs.

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