

Sr. Project manager, PDR

Job ID: 00414628

Job Function

Project Management Development

Schedule

Full-time

Location

United States-California
South San Francisco

Job type

Regular Employee

Company/Division

Pharmaceutical

Job Level

Manager

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

Position Purpose:

- The Senior Regulatory Global Project Manager is expected to serve as a strategic partner with Global Regulatory Leaders (GRLs), work with the GRL and the cross-functional global filing team members to define regulatory filing strategy, convert the strategy into an executable plan, and facilitate flawless execution of the plan to enable successful global filings and Health Authority interactions;
- Applies project management methodology and disciplines to improve the efficiency and effectiveness of the global filing team;
- Contributes to the efforts of building templates, tools and processes to optimize filing team performance;
- Serves as business partner for the assigned TA (Therapeutic Area) in PDR, working closely with the TA Head, brings excellent project management service offering to the TAs, and also bring TAs' request/feedback to the Regulatory Business Excellent (RBE) to help further optimize the performance and service offering by RBE.

Major Responsibilities and Accountabilities:

- Provides appropriate level of Project Management service, and tactical leadership to multiple global filing teams based on the agreed scope of work and business need;
- Takes accountability for all project management aspects and works effectively and

- closely with the GRL or Team Leader;
- Drives creation and updates of a high quality filing timeline using MS Project with clearly defined activities, interdependencies, duration, task owners and planning assumptions; collaborates closely with the GRL and team members to coordinate, prioritize and aligns team's activity in support of the project plan and ensure a structured approach to activity execution, and the efficient utilization of resources;
- Actively tracks the progress of the deliverables, and partners with GRL to create reports and trackers to ensure clear and transparent communication to key stakeholders;
- Works closely with team to identify and manage the activities which are on critical path and the critical activities that have the potential to become critical path activities; identifies the potential risks that could impact the timeline and PTS of a filing, and work with team to define a mitigation plan;
- Effectively facilitates filing team meetings with high quality meeting agenda and minutes;
- Maintains an action item tracking log, drives the completion of the action items, and documents the resolution of the action items;
- Facilitates team communication, monitors the activities of the project team to ensure constructive team dynamics, effective communication and progress in conformance with project scope and timelines;
- Maintains proper online documentations of filing related project documents;
- Assists GRL on preparation, organizing and conducting lessons learned sessions post filing;
- Through support of the projects, identifies near-term improvement opportunities to leverage and/or enhance PDR PMO's project management knowledge, process, tools, and templates to potentially increase efficiencies, accelerated activities and standardize processes.

Who You Are

Qualifications:

- Bachelor's degree in a scientific discipline preferred.
- Proficiency with common project management tools including MS Project.
- PMP (Project Management certification) or equivalent is a plus.

Experience and/or Competencies Required:

- Five or more years of project management experience in cross-functional drug development projects in pharmaceutical/biotech industry
- Experience supporting a global team is a plus
- Strong project management and team facilitation skills
- Demonstrated ability to collaborate and negotiate business solutions in a complex and fast paced matrix global environment
- Strong written and oral communication skills with a proven ability to communicate effectively at all levels in the organization
- Team player with strong interpersonal skills, paired with strong partnering and performance consulting skills
- Ability to work independently and as part of a team
- Strong planning and organizational skills; able to multi-tasking, prioritize and organize high volume workflow; ensure attention to details and accuracy within required timeframe; have good judgment and able to balance efforts and quality of work
- High degree of customer focused sensitivity
- Global regulatory filing experience is required

- Position requires international travel
- Position requires ability for global video conference during peak international working hours (i.e., 4:00 – 7:00 PM GMT, 7:00 – 10:00 AM PST).

Genentech is an Equal Opportunity Employer.