Genentech
A Member of the Roche Group

Date: 03/13/19

Senior Portfolio / Program Manager, Regulatory PMO

Job ID: 201809-120485

Job Function
General Business Operations

Location
South San Francisco
California
United States of America

Company/Division
Pharmaceuticals

Schedule
Full time

Job type
Regular

Job Level
Individual contributor

The Position

The Product Portfolio Management Office (Product PMO) provides PTR with services in product portfolio management, product project management, TRT program management and knowledge management. The PMO works closely with the Biologics and Small Molecule platforms to deliver a holistic strategic plan for the Biologics and Small Molecules projects portfolio and to identify common regulatory and operational themes and trends between products and projects. The Product PMO collaborates with all functions in PTR to increase efficiencies, productivity and/or quality of the way the Technical Regulatory Teams (TRTs) operate. The Product PMO portfolio management supports product project prioritization; enables the product portfolio resourcing and budgeting processes and facilitates PTR product portfolio reviews. The Product PMO Portfolio Manager will actively contribute to these services. She/he will be responsible of the PTR Product Portfolio (Biologics and/or Small Molecules) and will be responsible to continuously improve processes that the Product PMO uses to resource, oversee, and report on projects at both the project and portfolio levels. As a member of the Product PMO, he/she will drive continuous improvement of the TRT program infrastructure and the collaborations with external partners such as Pharma Technical Development (PTD), Pharma Technical Supply (PTS), Pharma Development Regulatory (PDR), etc.

The Product PMO Portfolio Manager will support the knowledge management efforts in PTR by adhering to processes and fostering behaviors to ensure that critical regulatory information is consistently and easily available to PTR users. The Product Portfolio Manager will be in contact with leaders in key partner organizations regarding TRT and TRL interactions, roles and responsibilities and deliverables.

This role will build effective relationships with Technical Regulatory Leads (TRLs), Technical Regulatory Team (TRT) Members, PTR Operations Business Excellence, and other portfolio stakeholders and consumers of technical regulatory program and portfolio data.

Product Portfolio Management (Biologics and/or Small Molecules) – Develop/Adapt existing

processes to accomplish the following:

- Collect product project specific information from TRLs, TRTs, and technical managers including: Technical Regulatory Strategies; Regulatory product health and project execution performance information (adherence to schedule, scope / strategy, resources) and Product and projects risks.
- Aggregate and analyze project data to identify, analyze, and manage portfolio-level trends and generate recommendations to PTR strategy including portfolio/business risk mitigation, staffing levels, workforce skills development, process improvements, cross-platform opportunities, etc. Develop and publish portfolio reports.
- Collaborate with senior management and other stakeholders to identify portfolio data needed for decision making at various governance bodies and levels of functional leadership.

Work closely with the platforms to deliver a holistic strategic plan for their projects portfolio and to identify common regulatory and operational themes and trends between products and projects.

Establish governance and/or organization to manage the product portfolio process. Organize and/or manage the Product Portfolio Reviews. Enable the product portfolio resourcing and budgeting processes.

Develop, implement, monitor and evolve regulatory program management tools, methodologies and processes.

Drive continuous improvement of the TRT program infrastructure and of collaborations with external partners such as PTD, PTS, PDR, etc.

Support the knowledge management efforts in PTR by adhering to processes and fostering behaviors to ensure that critical regulatory information is consistently and easily available to PTR users.

QUALIFICATIONS

Education & Experience:

- MS or Ph.D. in a technical field with 10 years in the biotech industry, including 5+ years proven experience leading and or managing teams in a matrix environment.
- Sound knowledge of drug development processes. Well-versed in technical lifecycle of small molecules and biologics, and familiarity with technical regulatory requirements and planning of regulatory strategy.
- Previous technical regulatory experience a plus.
- Previous people management experience a plus.
- Demonstrates, or has proven abilities to demonstrate PTR and Roche Core Competencies.
- Demonstrates, or has proven abilities to demonstrate Roche Values and Leadership Competencies.
- Strong project management and communication skills.
- Evidence of effective skills in people and team development.
- Highly competent in MS office applications including Excel, Powerpoint, Word, Project, etc.
- Strong influencing skills; consistently achieves targeted results without authority and by leveraging his/her expertise, business knowledge, interpersonal skills, organizational savvy and relationships.
- Strong partnering skills; has exceptionally strong and highly effective working relationships with internal and/or external customers, partners and stakeholders.

- Excellent interpersonal and organizational skills, including understanding of key change management concepts and methodologies; Proven abilities to effectively lead, organize and prioritize work.
- Must work well as member of a diverse global team and in a proactive, positive and collaborative manner; Ability to lead cross-functional teams.
- Comfort around all levels of staff and management; maintains a confident stance, stays focused and on-point, and is able to raise problems or challenges in a productive and competent manner.
- Exceptional skills in assessing, summarizing and presenting business or operational priorities and decision-points for effective, timely and efficient management/executive decision-making.
- Strategic orientation. Can effectively look out several years and project business or operational implications, trends, risks, uncertainties and/or opportunities.
- Able to deal with ambiguity and constant change.
- Able to work independently with minimal supervision.
- Able to function effectively in a fast-paced, multi-tasking environment.
- International or global business experience and cultural awareness preferred.
- Ability to travel up to 20%

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.