Senior Manager, Project Management

Description

Job Summary

The Manager/Senior Manager, Project Management (PM) directly supports the Regulatory Affairs (RA) department and is responsible for the planning and successful execution of global regulatory projects and submissions. The PM will lead cross-functional submission teams that are responsible for developing these regulatory submissions. In addition, the PM will ensure these regulatory deliverables are aligned and incorporated into Clovis' global Project Team plans throughout all phases of Product Development.

The Clovis RA department is responsible for regulatory submissions worldwide that support our ongoing product development and marketing authorizations across therapeutic areas within oncology. Since Clovis Oncology operates a matrix organization, the PM must be able to work effectively with functional and cross functional peers within a team environment.

The RA department is high profile within the organization and is very much "hands on." Regulatory components to projects are typically complex and strategic, and consequently, the PM role requires an ability to manage multiple tasks, to work with all levels of the organization from Senior executives to Specialists, and to have a high level of organizational and communication skills. In addition to working with our internal teams, the PM may interact with our partner organizations where we are working on regulatory projects/documents together.

Job Responsibilities

- Planning, tracking, and managing the progress of regulatory projects to defined milestones and regulatory operations submission schedules. Projects include US NDA and EU/ROW MAs and associated maintenance activities. Using Veeva, tracking regulatory commitments and timelines for maintenance activities such as Postmarketing Commitments and Follow-up Measures, and ensuring appropriate submissions are made in accordance with applicable requirements and within deadlines.
- Identify and coordinate regulatory team resources, management of risks across projects and management of project dependencies and critical path using appropriate tracking tools
- Work directly SVP Regulatory Affairs in managing departmental team meetings and initiatives
- Develop and facilitate team planning sessions including RSS (Regulatory Submission Subteams) by setting agendas, providing minutes and following up on action items
- Deliver minutes, progress reports, and other means for Regulatory and submission team communication
- Where requested, support drafting and management of regulatory project budgets
- Liaise with internal and key stakeholders, alliance partners and outside consultants

Qualifications

- Strong project management, organizational, analytical, communication, problem solving, prioritization and negotiation skills
- Strong editing and writing skills
- Resourceful and persuasive at following up with team members to resolve issues/questions
- Demonstrated ability to multi-task and prioritize effectively; strong attention to detail; exhibits creativity and flexibility in a changing environment; and communicates effectively with a multi-site team
- Excellent documentation skills including detail-oriented, record maintenance/ tracking and understanding of document traceability;
- Highly motivated and enjoy working in a fast paced, challenging matrix environment
- Ability to interact cross-functionally at all levels internally within Clovis and externally with alliance partners/consultants/CROs
- Flexible relative to responsibilities since job scope/role will inevitably evolve as the company grows and matures
- Knowledgeable of regulatory submission processes for the US; international territories a plus
- Fluency with project tracking tools, e.g., MS Project and Excel, presentation tools, e.g., PowerPoint and content management systems, e.g., Veeva Vault

Education and Experience

- A minimum of a BS degree in a scientific or related discipline is required
- Minimum of 5 years of relevant pharmaceutical project management experience, with a focus on Regulatory Affairs-related activities (OR working knowledge of Reg Affairs activities)

Salary

The salary range for this position is $120,000-$160,000.

Working Conditions

- This is an office/home-based position with minimal (less than 10%) travel required.

To apply:

Please visit the Careers page on our website – clovisoncology.com.