



Guidance for Translational Stage Project Manager Qualifications

Role Description

- Facilitate effective planning with the Team to define key activities
- Drive execution of Team activities to meet project deliverables
- Drive closure of Team actions to enable advancement to next stage (e.g. pre-IND filing and FDA engagement for a candidate therapeutic) through an effective program review process

In partnership with the Principal Investigator, the Translational Program Project Manager (PM) is responsible for applying best practices, and facilitating effective communication to enable optimum (Therapeutic, Diagnostic, Device or Tool) Team performance as the project moves toward a regulated (or, for Tools, a production) environment. The PM should be familiar with and utilize a variety of processes and tools to manage the information flow & meetings (communication), Team dynamics, budget, schedule, compliance and project risk management. With these processes and tools, the PM will enable the Team to effectively perform in meeting their project milestones/deliverables.

The PM will proactively drive planning and execution of the project strategy; this will involve oversight of project plan execution through the close monitoring of critical path activities and the creation of contingency plans to resolve issues and achieve deliverables. The PM is responsible for promoting a collaborative team environment and maintaining positive team dynamics to enable on time execution. A strong emphasis on effective meeting management, transparent team communication, efficient decision-making, proactive risk management, conflict resolution and problem-solving is required.

Typical CV Requirements:

- B.S. or B.A degree, preferably in relevant scientific field, or the equivalent.
- Multiple years of relevant post-graduate experience,
- Drug and/or Medical Device development & commercialization experience is desirable
- Project Management best practices: communication, scheduling, budget & resource planning, team building and risk management
- Project Management Professional (PMP) certification considered an asset
- Solid knowledge and understanding of relevant FDA (or CMS) regulatory guidance documents (for Therapeutic, Device, Diagnostic projects)
- Demonstrated ability to work independently to manage complex projects with multiple priorities in a team-based environment
- Excellent oral and written communication skills (listening, negotiation, presentation, organizational and relationship-building) required