Director- Technical project leader

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REQ-10050671
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India

Περίληψη

The Technical Project Leader will, jointly with the CMC team, lead and manage all technical development activities for assigned small molecule projects within Technical Research & Development (TRD); represent TRD as core member in global project teams to define the global CMC strategy for the development, submission, approval and life cycle management of a product(s); maximize the support to local programs and partners; lead CMC teams with strong strategic focus, quality & environmental awareness, management capabilities, scientific and technical expertise; act as the TRD representative in complex projects involving external partners and/or highly innovative projects/processes.

About the Role

Major accountabilities:

- Performs strategic planning of more complex and/or accelerated projects with e.g., multiple candidates / scenarios, or of several projects with varying timescales. Has sense of urgency, aligns, and coordinates multiple activities in complex plans. Establishes realistic project timelines to achieve milestones and goals, organizes additional resources if needed to fulfill planning, tracks progress and takes actions if obstacles emerge or priorities change.
- Establishes technical development plans in line with priority classification of project, gated by clinical readouts as appropriate and with an enterprise view in consideration of overall portfolio priorities. Establishes high level summaries for presentation to management and stakeholders.
- Has advanced skill to identify, assess, manage, and communicate CMC risks / program risks. Due to seniority and experience, can handle more difficult risks, issues in more complex projects and handle multiple risks of DS/DP/Device even with junior CMC team members.
- Provides drug development expertise in addition to technical expertise.
- Follows standard process but at the same time thinks outside the box based on existing knowledge. Challenges the status quo, is curious and fosters creativity of team members and own creativity.
- Leverages existing knowledge and implements in EPT/GPT strategy. Continues to follow and stands behind EPT/GPT decisions.
- For complex late phase programs, Senior TPL supports defined work packages.
- Build relationships by identifying common interests and priorities with a variety of people inside and outside the organization. Has deeper understanding of current organizational structure, establishes networks and uses own network to resolve challenging situations and manage/drive change.
- Participates in boards and joins and/or can lead discussions in leadership teams.
- Is highly skilled in collaborative settings (i.e., external vs internal, CROs, DDs, in-/out-licensing settings).
- Approaches/analyzes issues and collaborates with other line functions for optimal solutions.
- Takes into account multiple stakeholder perspectives and approaches to find optimal solutions and build

commitment and consensus.
- Provides knowledge of industry, main competitors, customers and external environment – this includes healthcare industry and global industry, digital and technological advancements.
- Shares knowledge with CMC community, e.g., by lessons learned sessions.
- Uses knowledge and experience to challenge and influence CMC line functions and/or EPTs/GPTs in background of the overall drug development strategy / industry insight. Actively contributes to EPTs/GPTs beyond CMC line functions. Is able to navigate and manage the complexity of the dis-ease area GPTs.
- Leads DDs for assets in development. Is able to cope with time pressure and senior management exposure.
- Relates to people in an open, friendly, and accepting manner. Understands the formal and informal channels for exchange of ideas and provides constructive feedback.
- Reacts tactfully when receiving advice, instruction or critical feedback and openly gives and receives feedback.
- Remains calm and objective and demonstrates respect, composure, and professionalism during difficult circumstances, including difficult interpersonal situations. Learns to manage teams/stakeholders appropriately (utilizing their support). Brings forward sound proposals and shares lessons learned, without passing the blame.
- Anticipates setbacks and stays in control – takes criticism as intended for situations (not personally or toward particular individuals). Recovers quickly from problems and setbacks.
- Exhibits servant leadership and provides mentoring/coaching to junior TPLs, line functions and CMC team members to support their professional and personal growth.
- Leads by example and drives decisions.

Minimum requirements

- Successfully demonstrated several years (minimum of 2-3 years) of directly related experience as functional project leader and relevant experience as Associate TPL or equivalent.
- Has strong scientific/technical knowledge, understands technical development tasks.
- Is able to establish/maintain DS/DP/Device supply plan (in alignment with CSPL).
- Has fundamental knowledge of GMP and regulatory requirements.
- Has fundamental cross-functional knowledge (PK/PD, tox, clinical, commercial) regarding drug development.
- Manages end to end technical drug development and knowledge.
- Completed basic project management training.
- Potential extension (not mandatory): Basic/Bronze IQP training.
- Is adept at using and regularly uses/updates project management tools available in TRD (e.g. Gantt charts, MS Project, Resource Cockpit).
- Knows fundamental IT tools.
- Has effective presentation skills.

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