NOVARTIS

Senior Expert Technical Development- Drug Product Project Lead

Job ID
REQ-10014665
Juli 25, 2024
USA

Summary

#LI-Onsite

As a Cell Therapy Process Development Drug Product Project Lead (DP-PL) you will be accountable for Drug Product-related project activities. In this role you will lead, manage, coach and support the project sub-team by fostering a culture of innovation, empowerment, trust, learning, diversity and inclusion. As a DP-PL you will support the Novartis pipeline programs, representing Process Development function, operating as a single point of contact for Drug Product in cross-functional CMC Team; you will have a complete oversight of Drug Product related activities and you will retain accountability for DP-related project strategy and deliverables within your functional area.

About the Role

Major accountabilities:

- Leads the discipline sub-team, acts as a project manager and is accountable for all project activities within Process Development Drug Product line unit.
- Owns the discipline project strategy in alignment with the technical development plan (TDP), and represents the project sub-team discipline in the CMC team as a core member.
- Sets priorities and objectives within the DP sub-team in alignment with the TDP and the CMC objectives and updates CMC team on technical issues, risks and mitigation strategies.
- Oversees the study design, provides guidance to functional leads (FLs) ensuring adherence to project development strategy; is accountable and responsible to define the DP control strategy.
- Tracs project progress according to defined timelines, identifies roadblocks/risks and issues, develops solutions and mitigation plans/scenarios if required and proactively reports them to respective stakeholders and governance boards (e.g. CMC project teams, line function management, affected line function discipline(s) and other relevant project boards).
- Compiles and provides financial forecast for project-specific development activities needed to reach the program milestone.
- Manages project specific compliance aspects (e.g. change notifications, deviations).
- Assesses, consolidates and monitors resource needs and timelines for assigned projects and ensures resources are accurately reflected in the planning systems.
- Ensures DP development is compliant with quality principles and cGMP practice; is accountable for coordination and timely delivery of high-quality source documents for HA submissions, review of regulatory documents (e.g. CMC modules, briefing books); provides content to/is responsible for answers

to HA questions or Investigator Brochure.
- Stays at the forefront of the scientific and technical trends in his/her discipline through literature and participation in conferences and workshops.

Minimum Requirements:

- University degree in biotechnology, pharmaceutical technology or similar discipline
- 5-6 years (BS), 2-4 years (MS) or 0-3 years (Ph.D.) of related experience with pharmaceutical development (Drug Product).
- Thorough understanding of development processes, good knowledge of state-of-the-art technology/equipment, and knowledge of related basic regulations.
- Project excellence: Navigating through complexity and ambiguity, strong communication & presentation and organization and planning skills, excellent time management and planning abilities; inclusive in a decision-making process, strong leadership skills in a matrix set-up.
- Operational excellence: Demonstrates cross-functional problem-solving, critical data evaluation, continuous improvement mindset; advanced coaching and proven leadership skills.
- Organizational Savvy: Understanding organizational structures, working practices and strategy. Inclusive and collaborative across disciplines and geographies, excellent networking and relationship building.
- Stakeholder engagement: Excellent communication, negotiation, and interpersonal skills. Ability to work in interdisciplinary and cross-cultural teams; confident in managing expectations and conflict management.
- Business mindset: strategic thinking and planning, confident with risk management including quality & safety, resources and budget planning.
- Vision and Purpose: a role model to the functional team for creating a shared purpose; priorities and objectives setting

The pay range for this position at commencement of employment is expected to be between $124,000 and $186,000 /year; however, while salary ranges are effective from 1/1/24 through 12/31/24, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an “at-will position” and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients’ lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

Benefits and Rewards: Read our handbook to learn about all the ways we’ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Commitment to Diversity & Inclusion: The Novartis Group of Companies are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age,

sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

Skills:

- Coaching Skills.
- Data Science.
- Environment.
- Experiments Design.
- Health And Safety (Ehs).
- Laboratory Equipment.
- Manufacturing Process.
- Materials Science.
- Process Simulation.
- Project Management.
- Sop (Standard Operating Procedure).
- Technical Writing.

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EEO Statement :

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Major Accountabilities ~ Steigern Sie Ihr wettbewerbsfähiges Umsatzwachstum ~ Identifizierung und Priorisierung von Kunden mit hohem Potenzial durch Datenanalyse (HCPs und Stakeholder), die Verschreibungsentscheidungen beeinflussen ~ Steigern Sie die Vertriebsleistung durch die geschickte Orchestrierung positiver Kundenerlebnisse ~ Engagieren und Beziehungen aufbauen ~ Führen Sie wertorientierte Gespräche (persönlich und virtuell), um kritische Kundenherausforderungen, Entscheidungstreiber, Schwachstellen und Chancen zu verstehen ~ Personalisieren und orchestrieren Sie Customer Engagement Journeys für HCPs,

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