NOVARTIS

Senior Expert Science & Technology

Job ID
REQ-10044663
Mar 25, 2025
USA

Summary

#LI-Hybrid As a Cell Therapy Process Development Drug Product Project Lead (DP-PL) you will be accountable for Drug Product-related project activities. You will lead, manage, coach and support the project sub-team by fostering a culture of innovation, empowerment, trust, learning, diversity and inclusion. 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 complete oversight of Drug Product related activities and retain accountability for DP-related project strategy and deliverables within your functional area.

About the Role

Accountabilities

- Lead the discipline sub-team, act as a project manager, and be accountable for all project activities within the Process Development Drug Product line unit.
- Own the discipline project strategy in alignment with the technical development plan (TDP) and represent the project sub-team discipline in the CMC team as a core member.
- Set priorities and objectives within the DP sub-team in alignment with the TDP and CMC objectives, and update the CMC team on technical issues, risks, and mitigation strategies.
- Oversee study design, provide guidance to functional leads (FLs), and ensure adherence to project development strategy.
- Track project progress according to defined timelines, identify roadblocks/risks and issues, develop solutions and mitigation plans/scenarios, and proactively report them to respective stakeholders and governance boards.
- Compile and provide financial forecasts for project-specific development activities needed to reach program milestones.
- Manage project-specific compliance aspects (e.g., change notifications, deviations).
- Assess, consolidate, and monitor resource needs and timelines for assigned projects.
- Ensure DP development is compliant with quality principles and cGMP practice.
- Stay at the forefront of scientific and technical trends in the discipline through literature and participation in conferences and workshops.

- Compile and monitor critical raw material supply needed for development activities in scope of the project.
- Support Tech Transfer Lead in setting up transfer strategy and supports TT-related activities.
- Organize PD-PL project review meetings, updates project-specific risk-register and proposes relevant risk-mitigation strategies.
- Contribute and supports decisions for clinical manufacturing site selection and perform a technical fit gap analysis as needed
- Drive root cause investigations (RCIs) in his/her area of expertise
- Represent the PD functional area as an *ad hoc* member in early project teams (EPT), Global Program Teams (GPTs) or other boards, as required.

Requirements:

- Successfully demonstrated experience with cell therapy pharmaceutical development (Drug Product)- at least 5-6 years (BS), 2-4 years (MS) or 0-3 years (Ph.D.) of related
- Thorough understanding of cell therapy development processes, good knowledge of state-of-the-art cell therapy technologies & equipment, and knowledge of ATMP-related health authority 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

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between: $119,700 and $222,300/year; however, while salary ranges are effective from 1/1/25 through 12/31/25, 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

This position will be located at our East Hanover, NJ site and will not have the ability to be located remotely. Please note that this role would not provide relocation, and only local candidates will be considered.

Company will not sponsor visas for this position.

Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

Accessibility & Reasonable Accommodations

The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Division
Development
Business Unit
Universal Hierarchy Node
Location
USA
State
New Jersey
Site
East Hanover

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Employment Type
Regular
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