

# Senior Expert Technical Development - Cell Therapy Process Development Project Lead

Job ID  
REQ-10025331

10月 15, 2024

USA

## 摘要

As a Cell Therapy Process Development 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 in cross-functional CMC Team. You will have complete oversight of Cell Therapy Process related activities and retain accountability for Process Development-related project strategy and deliverables within your functional area.

## About the Role

Major accountabilities:

- Lead the discipline sub-team, act as a project manager, and be accountable for all project activities within the Process Development 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 Process Development 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.

#### Minimum Requirements:

- University degree in biotechnology, pharmaceutical technology or similar discipline
- Successfully demonstrated at least 5-6 years (BS), 2-4 years (MS) or 0-3 years (Ph.D.) of related experience with cell therapy process development.
- 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

#### Work Experience:

- People Challenges.
- Critical Negotiations.
- People Leadership.

- Operations Management and Execution.
- Collaborating across boundaries.

Skills:

- Budget Management.
- Coaching Skills.
- Data Science.
- Experiments Design.
- Laboratory.
- Problem Solving Skills.
- Process Simulation.
- Project Management.
- R&D.

Languages :

- English.

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部门

Development

Business Unit

Innovative Medicines

地点

USA

站点

East Hanover

Company / Legal Entity

U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Alternative Location 1

Cambridge (USA), USA

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work  
No

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