# Exec Director Process Development Cell Therapy

Job ID
391878BR
Mai 09, 2024
USA

## Zusammenfassung

Location: East Hanover, NJ The Executive Director, Process Development for Cell Therapies, leads the Process Development function for TRD Cell & Gene Therapies, comprising of multiple functions. Shape, develop, and lead its strategic and scientific direction and drive operational excellence in line with TRD Biologics & CGT vi-sion and strategy. Acts as an ambassador for the Novartis Culture – Inspired, Curious and Unbossed.

## About the Role

**Your Key Responsibilities:**

• Leads Process Development function for Cell Therapies in TRD, comprising multiple develop-ment projects in various locations
• Develop, implement, drive and regularly refine the global strategy for process development in line with TRD CGT vision and strategy, as well reflecting customer needs and expectations
• Build and maintain an effective, agile, high performing multi-site organization that consistently supports existing and future product portfolio. Ensure efficient processes and business practices, drive continuous, knowledge exchange and lessons learnt
• Ensure optimal resource allocation and appropriate make vs. buy decisions in alignment with project priorities, technology strategy and business impact in line with TRD CGT governance processes
• Optimize laboratory utilization and efficiency, while fully supporting clinical demands
• Closely work and align with partner functions within Cell Therapies, TRD CGT, and Biologics TRD.
• Establish and maintain strong business relations and interfaces to key partners and stakeholders such as NTO, NIBR, GDD, Quality, Procurement, RA CMC etc.
• Proactively shape the process development environment by fully utilizing internal and external know-how as well as cutting edge technologies, techniques and approaches, continuously push and operationalize innovation and data & digital initiatives in line with TRD CGT strategy
• Achieve a true culture of collaboration, empowerment, innovation, diversity and inclusion, trust, high performance and continuous learning
• Drive talent acquisition and retention, succession planning and professional development of all associates to fully unleash their potential
• Actively coach and develop direct reports
• Ensure compliance with all relevant regulations (e.g. ISEC, GMP and HSE) and establish related accountabilities within the organization
• Ensure high quality source documents and dossier modules (where applicable) for regulatory submissions
• As a member of the TRD CGT global leadership team, actively contribute to TRD CGT strategy, vision and operations; represent TRD CGT at cross-functional decision-/governance boards (as appropriate)

• Closely works with the partners within Research and Development organizations to expedite the advancement of Cell Therapies based pipeline projects toward successful IND filings.
• Provides technical expertise to guide the development of new and/or improved processes for consistent, high quality production.
• Provides authorship and/or feedback for the regulatory CMC packages related to the manufacturing processes for IND filings and applications for approval (BLA/MAA/NDA).
• Provides timely responses to process development requests from health authorities during the global filings of the product for ongoing approvals.
• Oversees and ensures the timely delivery of process development, qualification and transfer from PD to Operations for GMP manufacture.
• Oversees and ensures the timely delivery of all the post-approval commitments of commercial
• product to the health authorities.
• Manage day-to-day operations of the CT Process Development department.
• A member of the Global TRD CGT Leadership Team.

**Role Requirements:**

• Ph.D. in cellular biology, virology, chemical engineering, Molecular Biology, Biology, Genetics, Analytical/Organic
• Engineering and/or related natural science discipline
• 15 years of process experience in developing, qualifying, validating, and tech transferring manufacturing processes
• A combination of education and specialized cell therapy experience may be considered to meet the required years of experience for the level of this position.
• Knowledge in GxP compliance and data integrity is required to ensure smooth transition of the qualified method to Operations.
• Prior experience in the cell therapy and/or other advanced therapeutics is strongly preferred
• Proven track record of outstanding management and leadership skills to build and oversee a large, high-performing team (50+ members) with diversified expertise including cell therapies in CAR-T and/or human stem cells, gene editing, process development, transfer, and validation, and process automation.
• Demonstrated ability with well-established reputation in developing, transferring, and implementing innovative, value-added manufacturing processes from scratch.
• Diversified experience and knowledge in a wide spectrum of CMC development suitable for adequately producing cell therapeutics. Strong communication and presentation skills in English.

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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.

**Novartis Compensation and Benefit Summary:** The pay range for this position at commencement of employment is expected to be between $233,400- $350,400/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.

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