# Associate Director of BioAnalytics, Cell and Gene Therapy Analytical Operations

Job ID
REQ-10031531
Dec 16, 2024
USA

## Summary

Internal Title: Associate Director of BioAnalytics
Location: East Hanover, NJ, United States (On-site)
LI #onsite
Join Our Vision: At Novartis, we are on a transformative journey in cell and gene therapy, pushing the boundaries of medical innovation. We are currently seeking a dynamic and visionary Associate Director to spearhead our Cell and Gene Therapy Analytical Operations Bioanalytics group. This pivotal role is not just about leading a team; it's about shaping the future of cell and gene therapy.
As the Associate Director of BioAnalytics, you'll be at the forefront of our mission, guiding a talented group of Quality Control analysts dedicated to routine testing, method qualification, method validation and transfer activities for Novartis Cell and Gene clinical products. Reporting to the Head of Cell and Gene Therapy Analytical Operations, you will be a vital link among Analytical Development, Pilot Plant manufacturing, Quality Assurance and Technical Operations.

## About the Role

**Key Responsibilities:**

- Lead and manage a team of Quality Control analysts to perform routine product release and stability testing, including compendial, molecular, flow cytometry, potency and liquid chromatography methods, for Novartis Cell and Gene products in the clinical phase.
- Oversee shift work, coordinate activities, and prioritize the assigned team to meet the required business timelines. Serve as the primary point of contact for communication to management during shifts.
- Lead and oversee method qualification, validation and transfer activities, including study design, reviewing, and approving study protocols and reports.
- Develop strategies for analytical method trending and routinely monitor analytical assay performance.
- Organize, plan, and support team members with analytical/technical questions and problem-solving to ensure the group's efficiency and accountability. Mentor and coach team members to facilitate career growth.
- Ensure that all activities, including training and equipment management, comply with current Good Manufacturing Practices and Health, Safety, and Environmental policies per the global/local Novartis policies and procedures.
- Lead and perform OOS (Out-of-Specification)/OOE (Out-of-Expectation) investigations. Manage change controls, deviations, and CAPA (Corrective and Preventative Actions) implementation.
- Support laboratory inspections and audits, including follow-up actions.

- Plan and manage resources and budget, including capital expenditures (CapEx).

**Requirements:**

- BS with a minimum of 8 years of industry experience in biotech or pharmaceutical companies, including at least 4 years of direct people management experience in a Quality Control environment.
- Flexibility to work different shifts, weekends, and overtime as required by business needs.
- Extensive knowledge and experience of Cell and Gene Therapy Quality Control methods including molecular assays (qPCR/dPCR/ddPCR, ELISA, NGS), Flow Cytometry, potency assays and liquid chromatography.
- Extensive experience working in a GMP environment.
- Strong communication, scientific writing, and presentation skills.

**Desirable Requirements:**

- Experience in resource and budget management.
- Experience with electronic systems such as SAP, LIMS, and Quality Management Systems.

**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

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**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.

**Novartis Compensation and Benefit Summary:** The pay range for this position at commencement of employment is expected to be between $144,000-$216,000/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.

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**EEO Statement:**

The Novartis Group of Companies are Equal Opportunity Employers who are focused on building and advancing a culture of inclusion that values and celebrates individual differences, uniqueness, backgrounds and perspectives. 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. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

**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.

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State
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Employment Type
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Shift Work

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