

Quality Control Scientist

Job ID REQ-10038970 Feb 01, 2025 USA

Summary

365 days a year, we aspire to be the best manufacturer of Cell & Gene therapies to ensure our patients have the treatments they need to live longer, healthier lives.

The Quality Control Scientist in an individual contributor role located in Morris Plains, NJ. The Quality Control Scientist will support patient throughput and compliance activities within the Quality department.

About the Role

Number of positions open: 3

Shifts Available:

Wed-Sat AM - 7:30am-6:00pm (1 position available)

Wed-Sat PM - 2:30pm-1:00am (1 position available)

Sun-Wed AM - 7:30am-6:00pm (1 position available)

Location: Morris Plains, NJ

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

Your responsibilities include, but are not limited to:

Patient Throughput

- Execute in-process and release testing on batches including, but not limited to, flow cytometry, IFNg potency, ELISA, qPCR, cell count and viability, sterility, and endotoxin.
- Perform data review, generate Certificates of Analyses for release of final produce in accordance with company procedure
- Work with cross-functional stakeholders to meet company timelines

Project Management

Helps maintain progress of projects

Compliance

 Ensures that all planned, executed, and documented activities are aligned with company and site objectives. Ensures adherence to all company policies and procedures relating to current Good Manufacturing
Practices, Standard Operating Procedures and Health, Safety and Environmental Protection regulations.

Support of Quality partners

- Assists Quality Control, AS&T, and Quality Assurance in investigations of assay-related issues.
- Executes and supports transfer of analytical methods between AS&T-QC, to other Novartis sites, and to CMOs.
- Provides timely response to requests for support of manufacturing deviations, investigations and change requests.

Other

- Performs or supports other tasks related to Quality and site operations, as needed
- Performs evaluation of new and existing analytical methods being transferred to or from the site by utilizing a risk-based approach.
- · Ability to lift 20lbs unassisted

What you'll bring to the role:

Requirements (mandatory: every candidate who is considered must have the qualifications described here. A candidate without these qualifications will not be considered or presented to the hiring manager)

- A minimum of a BA/BS in biology, chemistry, biochemistry, microbiology or other related science is required.
- At least 3 years of experience within pharmaceuticals of related testing laboratory is required
- Experience in Analytical Quality Control, method development, or a technical support function is required
- Demonstrated knowledge and skills in multiple analytical techniques is required
- Ability to prioritize and execute multiple tasks simultaneously under tight deadlines
- Strong verbal and written technical communication skills
- Strong interpersonal skill
- Proficiency using MS Word, Excel, and MS project is required
- Ability to communicate clearly with a variety of individuals in various aspects of Novartis operations.
- Detail-oriented with ability towards problem solving and solid decision-making abilities
- Strong written and verbal communication skills are essential

Desirable (not mandatory but are used to prioritize candidates who have described preferred qualifications but does not eliminate candidates from being considered)

- Understanding of ICH and FDA/EMEA GMP requirements
- Knowledge of cGMP, USP and FDA guidelines
- Knowledge of LIMS systems
- Knowledge of Quality Management Systems, such as Trackwise and 1QEM

Why Novartis?

766 million lives were touched by Novartis medicines in 2021, and while we're proud of this, we know there is so much more we could do to help improve and extend people's lives.

We believe new insights, perspectives and ground-breaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working.

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We believe our potential can thrive and grow in an unbossed culture underpinned by integrity, curiosity and flexibility. And we can reinvent what's possible, when we collaborate with courage to aggressively and ambitiously tackle the world's toughest medical challenges. Because the greatest risk in life, is the risk of never trying!

Imagine what you could do here at Novartis!

Commitment to Diversity & Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

Accessibility and Reasonable Accommodations: Individuals in need of a reasonable accommodation due to a medical condition or disability for any part of the application process, or to perform the essential functions of a position, please send an e-mail to tas.nacomms@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.

The pay range for this position at commencement of employment is expected to be between \$85,400 and \$158,600 per 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.

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

Customer-facing roles only:

While Novartis does not require vaccination for Covid-19 or proof of a recent negative test result for Covid-19 at this time, employees working in customer-facing roles must adhere to and comply with customers' (such as hospitals, physician offices, etc.) credentialing guidelines, which may require vaccination. As required by applicable law, Novartis will consider requests for reasonable accommodation for those unable to be vaccinated. This requirement is subject to applicable state and local laws and may not be applicable to employees working in certain jurisdictions. Please send accommodation requests to Eh.occupationalhealth@novartis.com.

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

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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 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 <u>us.reasonableaccommodations@novartis.com</u> 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

Operations

Business Unit

Innovative Medicines

Location

USA

State

New Jersey

Site

Morris Plains

Company / Legal Entity

U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

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Job ID

REQ-10038970

Quality Control Scientist

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