

Quality Control Supervisor

Job ID
REQ-10019303
Aug 15, 2024
USA

Summary

In this people management role, the Quality Control Supervisor will coordinate patient throughput and compliance activities within the Quality department as well as support development, validation, and external activities as needed.

About the Role

Shift: (Wed-Sat 7:30am-6:00pm)

Location: Morris Plains, NJ

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

Key Responsibilities:

- Execute, supervise, and review in-process, development, validation, and release testing on batches including, but limited to, flow cytometry, IFNg potency, qPCR, cell count and viability
- Follows GxP quality policies and procedures and track critical reagent inventory to allow for seamless operation
- Assist in planning and execution of laboratory studies
- Work with cross-functional stakeholders to meet company timelines and support and manage tracking and trending systems, and programs which assist in the testing, evaluation and monitoring of quality, assay performance and efficiency.
- Author, review, and approve Quality documents (i.e., protocols, reports, SOPs, test methods, technical documents, and risk assessments)
- Assists in evaluation of new and existing analytical methods being transferred to or from the site by utilizing a risk-based approach.
- Contributes, supports, and leads writing of OOS/OOE/OOT and deviation investigations.
- Drives CAPA outcomes
- Revise and/or create SOPs, forms, laboratory test records as required using appropriate electronic systems.
- Support internal and external audits of facility as a recognized SME.

Essential Requirements:

- BA, MS, or PhD in biology, chemistry, biochemistry, microbiology or other related science AND a Minimum of 5 years of experience in Analytical Quality Control, method development, or a technical support function.

- Demonstrated knowledge and skills in multiple analytical techniques and the ability to plan, prioritize and execute multiple tasks simultaneously under tight deadlines
- Experienced in writing OOS/OOE/OOT and/or deviation investigations
- Expertise in ICH and FDA/EMEA GMP requirements
- Ability to manage projects and lead teams utilizing modern project management methodology and tools. Knowledge of statistical tools and methods
- Strong verbal and written technical communication skills, ability to communicate clearly with a variety of individuals in various aspects of Novartis operations
- Knowledge of cGMP, USP and FDA guidelines, Knowledge of LIMS systems, Knowledge of Quality Management Systems, such as Trackwise and Knowledge of Change Control systems, such as Agile PLM
- Detail-oriented with expertise in problem solving and solid decision-making abilities.

Languages:

- English

Why Novartis: Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: <https://www.novartis.com/about/strategy/people-and-culture>

The pay range for this position at commencement of employment is expected to be between \$97,600 and \$146,400/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

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook.

Handbook. <https://www.novartis.com/careers/benefits-rewards>

Commitment to Diversity and Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patient and communities we serve.

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>

EEO Statement:

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.

Accessibility and 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 in order to perform the essential functions of a position, please send an e-mail to tas.nacomms@novartis.com 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.

<https://www.novartis.com/careers/careers-research/notice-all-applicants-us-job-openings>

Salary Range

\$97,600.00 - \$146,400.00

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 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.

Division

Operations

Business Unit

Innovative Medicines

Location

USA

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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