

QA Associate

Job ID REQ-10021174 Sep 18, 2024 USA

Summary

The Quality Operations Associate is responsible for first level, hands on, day-to-day cGMP facilitator role for all site related GMP activities. The QA Associate will interact directly with site staff, who are performing the daily operational functions in support of their effort to produce quality products. This role ensures that the quality strategy is implemented and that there is a continuous drive to improve product and process quality.

About the Role

Hours: 5 positions open. Various days and shifts are as follows:

Wed-Sat AM - 7:00am-5:30pm - 2 positions open

Sun-Wed PM - 2:30pm-1:00am (exact times may vary slightly) - 1 position open

Wed-Sat PM - 2:30pm-1:00am (exact times may vary slightly) - 2 positions open

Location: This role is on-site and located in Morris Plains. NJ

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

Major accountabilities:

Under the guidance of the Quality Assurance Manager provides oversight to various departments within Morris Plains.

- Review and approve batch records, Apheresis, Aborted and Invalid Assays, etc. to ensure adherence to Novartis policies, SOPs, and cGMP requirements.
- Conduct routine shop floor tasks related to aseptic operations including but not limited to ViMOS, APV program observations, walkthrough program, QA area release, etc.
- Under the guidance of the Quality Assurance Managers, perform triaging and initiatition of events (Quality Event, Deviation, Action, CAPA, etc.). Expected to work with and partner with cross functional departments during triaging.
- Actively engage in process improvement and Right First-Time initiatives at the Morris Plains site. Ensures adherence of appropriate regulations and Novartis quality standards.
- Write and/or review of Standard Operating Procedures (SOPs), as needed.
- Assist in providing documentation as needed for self-inspections and external audits.
- Champion a Quality Culture and ensure a safe working environment.
- Complete job-related training as required.

Demonstrates and role models the Novartis values and behaviors.

Minimum Requirements:

Education:

BA degree in Biological Sciences or equivalent relevant career experience may be accepted.

Work Experience:

- A minimum of 2 years of experience in a pharmaceuticals environment.
- Knowledge and understanding of cGMPs, keeping up to date with current industry issues and changing regulations.

Specific Professional Competencies:

- Excellent oral and written communication skills required.
- Demonstrate ownership of completing daily tasks and excellent interpersonal skills.
- Ability to work under direction of team members, independently, and as
- part of a team if necessary.
- SAP, 1QEM, MES, LIMS knowledge preferred

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 \$62,900 and \$94,300/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

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 <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

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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