

# **QA** Associate

Job ID REQ-10030319

11月 19, 2024

**USA** 

## 摘要

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.

Hours and Shifts: Sun-Wed 7:00am-4:00pm Sun-Wed 12:00 pm-10:00pm Wed-Sat 7:00am-4:00pm Wed-Sat 12:00pm-10:00pm

These positions are 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.

### About the Role

#### Major accountabilities:

- 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 initiation 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:

- Associate or BA degree in Biological Sciences or equivalent relevant career experience may be accepted.
- 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.
- Excellent oral and written communication skills required.
- Demonstrate ownership of completing daily tasks and excellentinterpersonal skills.
- Ability to work under direction of team members, independently, and as part of a team if necessary. Strives for simplicity and clarity.
- SAP, 1QEM, MES, LIMS knowledge preferred

The pay range for this position at commencement of employment is expected to be between \$62,900 and \$94,300 Annual; however, base pay offered may vary depending on multiple individualized factors, including market location, job-related knowledge, skills, and experience. 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 can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards

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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <a href="https://www.novartis.com/careers/benefits-rewards">https://www.novartis.com/careers/benefits-rewards</a>

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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 <a href="mailto:us.reasonableaccommodations@novartis.com">us.reasonableaccommodations@novartis.com</a> 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.

部门 Operations

Business Unit Innovative Medicines

地点 USA

站点 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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