QA Specialist

Job ID
REQ-10039683
Mar 07, 2025
USA

Summary

This position will be located at Morris Plains, NJ and will not have the ability to be located remotely.

The Quality Assurance Specialist is responsible for first level, hands on, day-to-day cGMP facilitator role for all site related GMP activities. They interact directly with site staff, who are performing the daily operational functions, Make, test, Release, 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 within the PU, QC labs, and other support areas.

#LI-Onsite

Key Responsibilities:
• Shopfloor Activities: Conduct routine shop floor tasks related to aseptic operations including but not limited to ViMOS, APV observations, walkthroughs, QA area release, and, QC Floor support, etc.
• Perform triaging of events on shopfloor for PU and QC laboratories as well as other support areas, ensuring that deviations records are initiated adequately in deviation management system.
• Review Activities: Review and audit production batch records, and/or QC related documentation, to ensure adherence to Novartis policies, SOPs, and cGMP requirements.
• Interface closely with PU and QC to assist with batch record/QC data review, release, and compliance issue resolution.
• Actively participate in process improvement initiatives aiming for Right First Time (RFT) on documentation and deviation reduction.
• Ensures levels of documentation are adequate and compliant to existing procedures.
• Write, review and approve Standard Operating Procedures (SOPs), Work Procedures (WPs), and Forms (FRMs), as needed.
• Release Activities: ensure timely review and release of Aphs and media batches, Area release, and related activities.
• Responsible for the PP/ FP final release of patient product ensuring timely and robust product disposition in accordance with GMP and license requirements. Ensure the Disposition process meets industry and Novartis expectations and requirements

About the Role

Desirable Requirements:

- BS/BA in Biological Sciences or equivalent relevant career experience may be accepted.
- 3 + 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 leadership ability and excellent interpersonal skills.
- Ability to work under minimal directionr, independently or as part of a team if necessary.
- Strives for simplicity and clarity.
- SAP, 1QEM, MES, LIMS knowledge preferred
- Experience in Deviation Management, batch disposition, Aseptic Techniques preferred

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $85,400 and $158,600/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.

Company will not sponsor visas for this position.

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

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. 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.

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
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
Apply to Job

Job ID
REQ-10039683

QA Specialist

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4. mailto:us.reasonableaccommodations@novartis.com
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Morris-Plains/QA-Specialist_REQ-10039683-1

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