QC Specialist Tech Resources & Compliance

Job ID
REQ-10020076
Sep 03, 2024
Etats-Unis

Résumé

-This position will support activities within the Quality Control department, with a focus on technical items for QC, compliance and continuous improvement. This role will utilize strong cGMP understanding and scientific knowledge to perform Change Controls, investigations, technical review, etc. This role requires strong project management and communication skills to coordinate and implement cross-functional projects, ensuring timely and compliant execution. This role is based 100% on-site.

Novartis is unable to pay relocation for this role so please ensure you are able to work from this location.

About the Role

Key Responsibilities:

- Authors QC investigations and meets all targets for timely closure and CAPA completion.
- Coordinate with Quality to ensure compliance and continuous improvement in the QC labs.
- Coordinates change control for method related changes.
- Perform technical review of QC assays for cGMP release and characterization testing, including but not limited to cell-based methods (potency, AA), PCR (ddPCR, qPCR), Immunoassays (ELISA), chromatography (HPLC-UV, HPLC-ELSD, HPLC-MS), AUC, compendial assays (Bioburden, pH) and electrophoresis (CE, Western Blot).
- Authors technical documents such as Protocols / Reports.
- Works with the greater QC team to ensure updates of SOP, WP, Form, etc.
- Supports regulatory inspections.
- Capable of delivering to assigned work schedule with attention to detail and accuracy.
- Perform laboratory testing as required.
- Other duties QC is responsible for, as assigned.

Requirements:

- Bachelor's degree in scientific disciplines such as Biochemistry, Biology, Microbiology or related field with 5 years’ experience in GMP environment.
- Excellent interpersonal, verbal and written communication skills with strong technical writing experience required. Previous investigation experience a plus.
- Proven ability to work effectively in a team environment. Collaborates cross functionally with other departments to achieve site goals.

- Works on problems of moderate scope where analysis of situations or data requires a review of a variety of factors.

- Exercises judgment within defined procedures and practices to determine appropriate action including critically thinking, troubleshooting and problem-solving skills.
- Normally receives general instructions on routine work, detailed instructions on new projects or assignments.
- Self-motivated, detail-oriented, and willing to accept temporary responsibilities outside of core duties.

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 $40.38 and $60.57 Hourly; 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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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.

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