Senior Scientist, Quality Control Analytics

Job ID
390774BR
Aug 15, 2024
USA

Summary

Manages Quality aspects & projects within area of responsibility. Ensures and supports overall GxP conformity & Compliance with the Novartis Quality Management Systems. Collaborate with team(s) in the design and execution of validation and other major projects. Provide employees with training and resources to meet or exceed customer requirements. Monitor processes and products to identify opportunities for continuous improvement. Serve as the subject matter expert on specific areas and techniques and proactively provides education technical knowledge and skills to less experienced scientists.

About the Role

Shift: (Sun-Wed 7am-5:30pm)

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:

- Perform Bioanalytical testing in support of clinical and commercial release strategies.
- Acts as liaison for other departments and/or external stakeholders in support of non-standard testing regimes
- Execute and supervise peer review of analytical data.
- Support and manage tracking and trending systems, and programs which assist in the testing, evaluation and monitoring of quality, assay performance and efficiency.
- Drives execution of method qualification/development & optimization/transfer as governed by protocols and/or under the supervision of senior lab staff.
- Contribute, supports and lead writing of change controls, OOS/OOE/OOT and deviation investigations.
- Supports laboratory management in drafting analytical response/strategy documents.
- Assists and supervises equipment and metrology teams in troubleshooting equipment issues
- 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.

Key performance indicators:

- Flawlessly delivers quality results on time to all customers, internal and external.

Essential Requirements:

- Minimum of 5 years' experience in the Pharmaceutical/Biotechnology industries conducting QC testing, release testing and coordinating the activities of a QC laboratory.
- Thorough knowledge of cGxP expectations
- Thorough general knowledge of bioassay test methods (e.g. Elisa, Flow cytometry, qPCR, cell culture)
- SME level knowledge of a particular area of bioanalytical testing
- Experienced in writing OOS/OOE/OOT, and/or deviation investigations
- Knowledge of LIMS systems.
- Experience in supporting internal and/or external laboratory audits
- Advanced written and verbal communication skills as well as advanced experience in the use of computer-based systems and applications associated with bioanalytical testing

Desirable Requirements:

- Knowledge of ICH, Eur. Ph., USP and FDA and JP guidelines preferred, but not necessary
- Experience writing change controls preferred, but not necessary

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

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

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
Apply to Job

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

iframe{ width: 100%; margin-top: 3rem; } @media screen and (max-width: 767px){ iframe{ height: 30vh !important; } } @media screen and (min-width: 768px){ iframe{ height: 34vh !important; } }
Job ID
390774BR

Senior Scientist, Quality Control Analytics

Apply to Job

Source URL: *https://qa1.novartis.us/careers/career-search/job/details/390774br-senior-scientist-quality-control-analytics*

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture

2. https://www.novartis.com/careers/benefits-rewards
3. https://talentnetwork.novartis.com/network
4. https://www.novartis.com/about/strategy/people-and-culture
5. https://talentnetwork.novartis.com/network
6. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Morris-Plains/Senior-Scientist--QCA_390774BR-1
7. https://talentnetwork.novartis.com/network
8. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Morris-Plains/Senior-Scientist--QCA_390774BR-1