🕛 NOVARTIS

Supervisor, QC Chemistry

Job ID REQ-10028472 Nov 05, 2024 USA

Summary

Location: Indianapolis, IN #LI-Onsite

About this role:

In this people management role, the QC Chemistry Supervisor works with the Quality Control team in supporting our efforts of RLT therapy. This role is responsible for the day-to-day oversight of the QC Chemistry team including raw material testing and final product testing.

About the Role

Key Responsibilities:

- Supervision of laboratory personnel.
- Provide oversight for personnel work schedules as well as for scheduling and completion of testing and documentation.
- Provides oversight towards QC laboratory equipment maintenance.
- Expertise in one or more of the following methodologies: HPLC/UPLC, wet chemistry, TLC, endotoxin, radionuclidic identity by half-life, environmental monitoring, sterility
- Maintain the laboratory and laboratory procedures/processes in a constant state of inspection readiness.
- Ensure personnel are appropriately trained and cross-trained.
- Author, review, and approve technical documents.
- Ensure trending reports are completed and approved within established timelines.
- Support 5S and Lean Laboratory implementation and sustainability.
- Provide support of laboratory related manufacturing investigations, CAPAs, and change controls.
- Ensure safety requirements are met and maintained.
- Perform other job duties as assigned.
- · Design and execute method transfers/qualifications/validations based on Regulatory guidelines and industry best practices.
- Collaborate with other groups to drive project success.
- Troubleshoot method challenges.
- Manage method development and optimization activities as needed.

Essential Requirements:

- BS or MS in Biology, Chemistry, Microbiology or other related science.
- Minimum of 5 years of relevant experience in the pharmaceutical, biologics, medical device, or advanced therapy medicinal products industry. 1/3

- Previous supervisory experience is recommended but not required.
- Working knowledge of aseptic manufacturing, cGMPs, GLPs and applicable compendial and regulatory guidelines (e.g. FDA, EP, JP)
- Thorough knowledge of analytical and microbiological test methods.
- Experience with LIMS.

Commitment to Diversity and Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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? <u>https://www.novartis.com/about/strategy/people-and-culture</u>

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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 <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 State Indiana Site Indianapolis Company / Legal Entity U469 (FCRS = US469) AAA USA Inc. Functional Area Quality Job Type Full time Employment Type Regular Shift Work No Apply to Job

Job ID REQ-10028472

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