

Supervisor, QC Chemistry

Job ID REQ-10028472 Nov 05, 2024 USA

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.
- 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.

Role Requirements

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

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Division

Operations

Business Unit

Innovative Medicines

Location

USA

Site

Indianapolis

Company / Legal Entity

U469 (FCRS = US469) AAA USA Inc.

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

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