Supervisor, QC Chemistry

Job ID
REQ-10028472

11月 05, 2024

USA

摘要

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.
- 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.

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Indiana

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U469 (FCRS = US469) AAA USA Inc.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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