

Analytical Expert

Job ID
REQ-10047730

Apr 22, 2025

Italy

Summary

Design and plan scientific experiments as well as report and interpret results/outcome in line with the overall TRD RLT project strategy for RLT Drug Substance(s) and Drug Product(s) in development. Ensure project knowledge generation and preparation/timely delivery of supplies with high quality and state of the art standards. Contribute to the analytical project strategy definition; drive scientific and operational excellence and thereby contribute to overall TRD RLT strategy and goals.

About the Role

Key responsibilities:

- Execute and report RLT DS and/or DP analytical activities through advanced analytical science and technologies following agreed timelines and quality standards.
- Coordinate analytical aspects of project development for RLT and align the analytical strategy

with APL and DPPL/FPL.

- Develop and disseminate best practices with strong scientific expertise within the analytical project team.
- Create analytical documents supporting the analytical and global project strategies based on project phase, ensuring availability of all relevant GMP and source documents.
- Carry out and qualify analytical methods in line with ICH guidelines and specific references to quality control of radiopharmaceuticals.
- Assist in setting specifications suitable for the current development stage, aligning with the TRD RLT project team.
- Aid in the transfer of analytical procedures to manufacturing sites and radiopharmacies.
- Adhere to relevant SOP 's, GLP, GMP, OQM, HSE, ISEC and AdAcAp/Novartis guidelines and cultivate a strong team spirit.

Essential requirements:

- Hold a Master ' s degree in chemistry, pharmaceutical technology, or a related degree with a minimum of 2 years' industry experience in analytical chemistry and/or radiochemistry development and/or quality control.
- Proficient in English (both oral and written), with the preferred knowledge of the site language.
- Understands GMP principles, current and anticipated regulatory and quality expectations specifically within the radiopharmaceutical industry.
- Experienced in writing CMC documents for regulatory submissions and responding to health authority inquiries.
- Mindful of safety measures when handling chemicals, potentially hazardous materials, and equipment.
- Detail-oriented and committed to quality.
- Possesses good communication skills, including presentation and scientific/technical writing.
- Demonstrates excellent problem-solving and decision-making skills.

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部門

International

部門

Innovative Medicines

国

Italy

勤務地

Ivrea

Company / Legal Entity

IT58 (FCRS = IT058) Advanced Accelerator Applications Italy Srl

Functional Area

Research & Development

職種

Full time

雇用形態
Regular

Shift Work
No

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