RLT Analytical Expert (m/f/d)

Job ID
REQ-10015153
déc 11, 2024
Italie

Résumé

Location: Ivrea, Italy
Role Purpose:
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

Role Responsibilities:

- Design, plan, interpret (if applicable) and report analytical activities for RLT DS and/or DP applying state of the art analytical science and technologies (e.g., analytical method developments, validations transfers, stability) according to the agreed timelines and appropriate quality standards.
- Coordinates analytical activities for RLT related aspects of project development and aligns analytical strategy with RLT APL and DPPL/FPL.
- Build-up and share best practices, bring strong scientific and technical expertise within the analytical project sub team, analytical scientists and across the organization. Support the FPL and DPPL in the analytical activities required during formulation and process development (e.g. HPLC chemical and radiochemical purity methods, content by UV, identity, pH, osmolality, visible particles).
- Design and author analytical documents supporting the analytical and the global project strategies based on project phase. Ensures availability of all relevant GMP and source documents for development projects.
- Support the execution and qualification of analytical methods in accordance with ICH guidelines, where appropriate, and with specific references to quality control of radiopharmaceuticals.
- Contribute to setting specifications appropriate for the current development stage and in alignment with the TRD RLT project team.
- Participate in the transfer of analytical procedures to manufacturing sites and radiopharmacies. Follow the appropriate SOP’s, GLP, GMP, OQM, HSE, ISEC and AdAcAp / Novartis guidelines.

Essential Requirements:

- Minimum: Master’s degree in chemistry, pharmaceutical technology, or equivalent scientific degree with minimum 2 years of successful industry experience in the field of analytical chemistry and/or

radiochemistry development and/or quality control.
- Fluent knowledge of English (oral and written). Desirable knowledge of site language.
- Proficiency in quality principles driving drug development such as GMP; clear understanding of current and anticipated regulatory and quality expectations preferably in the radiopharmaceutical industry.
- Good experience in writing CMC documents for regulatory submissions and responding to health authority questions.
- Awareness for safe handling of chemicals, potentially dangerous materials, and equipment.
- Quality-oriented with attention to details

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Job Type

Full time
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