RLT Analytical Product Project Leader (m/f/d)

Job ID
REQ-10015150
Jul 11, 2024
Italy

Summary

Location: Ivrea, Italy

Role Purpose:
Define, lead and manage the analytical project strategy including the overall analytical control strategy for Drug Substance(s) and radiopharmaceutical parenteral Drug Product(s) in line with the overall CMC project development plan; ensure project specific high quality analytical submission documents. Support / mentor analytical team members and thereby contribute to the overall Technical Research and Development strategies and goals

About the Role

Role responsibilities:

- Define and develop an overall science and quality driven analytical project strategy including contingency plans and risk evaluations for RLT DS and RLT DP.
- Ensure transparent communication to the appropriate management level and / or to any other relevant project team members(s).
- Be a core member of the TRD sub-team representing RLT Analytical Science; co-own the technical development together with the DSPL and RLT DPPL, actively contribute to the definition of the overall technical development plan.
- Lead & coordinate, together with RLT analytical experts and subject matter experts, analytical activities (such as method development and validation, DS/DP stability, DS/DP release, reference nomination and transfer activities) across all analytical sites and partnering functions.
- Accountable for driving the testing strategy of RLT DS/DP and specifications setting. Be the RLT Analytical Science project representative in peer review and governance boards as well as in internal and external audits.
- Support the assessment, forecast & monitoring of monthly resource needs and reflect in TRD planning tools (internal/external costs and FTE requirements) ensuring budget adherence.
- Ensure the creation of an overall high-quality control strategy with partnering functions (CHAD, PHAD) and the documentation of the analytical/testing control strategy (e.g. SSS, risk assessments).
- Accountable for handover of analytical documents to internal and external partners (for e.g., including Health authority questions /CMC modules / Manufacturing & supply operations etc.) Understand & actively lead the interactions of project related RLT analytical activities across sites and line functions. Support EPM colleagues in outsourcing projects and provide input to QA agreements.

Essential Requirements:

- Minimum: PhD in chemistry, pharmaceutical technology, or equivalent scientific degree with minimum 5 years of successful industry experience in the field of analytical chemistry and/or radiochemistry development and/or quality control with project management experience.
- 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.
- Strong experience in writing CMC documents for regulatory submissions and responding to health authority questions.
- Strong experience with outsourcing and coordinating work done by CRO/CMOs including technical overview of agreement set up.
- Awareness for safe handling of chemicals, potentially dangerous materials, and equipment.

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Division
International
Business Unit
Innovative Medicines
Location
Italy
Site

Ivrea
Company / Legal Entity
IT58 (FCRS = IT058) AAA Italy Srl.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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