

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

Job ID
REQ-10015150
Jul 11, 2024
Italia

Resumen

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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Thousands of people die of cancer around the world every day. At Advanced Accelerator Applications, a Novartis company, our mission is to transform lives through radioligand therapy in nuclear medicine to fight several leading types of cancer. How will we continue to be on the cutting edge of medicine? We believe new groundbreaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working. We believe our potential can thrive and grow in an unbossed culture underpinned by integrity, curiosity and flexibility. And we can reinvent what's possible, when we collaborate with courage to aggressively and ambitiously tackle the world's toughest medical challenges. Because the greatest risk in life, is the risk of never trying!

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División

International

Business Unit

Innovative Medicines

Ubicación

Italia

Sitio

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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