

RLT Drug Product Project Lead (m/f/d)

Job ID
REQ-10015141
Jul 11, 2024
Italia

Resumen

Location: Ivrea, Italy

Role Purpose:

Leads and manages all Drug Product (DP) project activities linked to the development of radiopharmaceutical parenterals (both ready to use and freeze dried products). Supports & coaches team members, participates in scientific teams and contributes to the overall Technical Research and Development strategies and goals. Designs, plans, performs, interprets, and reports the results of scientific experiments for the preparation and timely delivery of drug product.

About the Role

Role Responsibilities:

- Leads and manages all formulation and process development activities for assigned projects.
- Support the development and the qualification of analytical methods together with the AS&T team leader in accordance with ICHs guidelines and internal SOPs.
- Represents DP project teams in TRD sub-team, with strong sense of accountability and responsibility.
- Develops sound DP project strategy including contingency planning and risk assessments in line with the overall TRD project plan, development guidelines (as applicable), SOPs and TRD/RLT strategy.
- Monitors project plans and ensures timely availability of agreed deliverables. Proactively communicates overall project strategy, key issues, and any other critical topics in a timely manner to the appropriate management level, to the TRD project leader and/ or to any other relevant project team member(s).
- Ensures adherence to the EP/LP project review process through relevant governance boards. No delays or missed reviews due to poor planning. Full compliance to other governance board processes, e.g. DMC. Ensure high quality documentation and pre-reads are provided per guidelines to facilitate these reviews.
- Ensures support to due diligence as applicable. Ensures availability of pre-requisites for transfer of projects to other sites as applicable (e.g. licenses, equipment, resource plan).
- Ensures application of IP process for all projects assigned and that all IP is accurately captured.
- Ensures contribution to respective Network deliverables and cross-functional workstreams/initiatives and ensure sharing of actions and learnings across global teams.

Essential Requirements:

- Minimum: PhD in Pharmaceuticals or related sciences with a minimum of 6 years of proven experience within the pharmaceutical/biotech industry or a Master's degree with a minimum of 8 years experience.

- Fluent knowledge of English (oral and written). Desirable knowledge of site language.
- Broad and profound understanding of development activities and processes in pharmaceutical sciences. (early phase and late phase development)
- Excellent knowledge of laboratory and/or technical tools (e.g. Quality by Design, statistical software, Process Analytical Technology).
- Strong experience with outsourcing and supervising work done by CRO/CMOs including technical overview of agreement set up.
- Strong experience in writing CMC documents for regulatory submissions and responding to health authority questions.
- Solid understanding of relevant GLP, GMP regulations and policies.
- Strong presentation skills and scientific/technical writing skills.

Why Advanced Accelerator Applications?

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! Imagine what you could do here at Novartis!

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International
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Innovative Medicines
Ubicación
Italia
Sitio
Ivrea
Company / Legal Entity

IT58 (FCRS = IT058) Advanced Accelerator Applications Italy Srl

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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