RLT Drug Product Project Leader

Job ID
REQ-10045286
Mar 28, 2025
Italy

Summary

Location: Ivrea, Italy

Role Purpose:
Leads and manages all Drug Product (DP) project activities linked to the development of radiopharmaceutical parenteral, 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 (TRD) 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 Pharmaceutics 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.

Commitment to Diversity and Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Division
Development
Business Unit
Innovative Medicines
Location
Italy
Site
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

Apply to Job

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Job ID
REQ-10045286

RLT Drug Product Project Leader

Apply to Job

Source URL: *https://prod1.novartis.com/us-en/careers/career-search/job/details/req-10045286-rlt-drug-product-project-leader*

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Ivrea/RLT-Drug-Product-Project-Leader_REQ-10045286-2
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Ivrea/RLT-Drug-Product-Project-Leader_REQ-10045286-2