

RLT Formulation Project Leader

Job ID
REQ-10013628
Sep 03, 2024
Italy

Summary

Create and drive with scientific & technological excellence the formulation development in close collaboration with operations, analytics, engineering and relevant SMEs, QA and the project DPPL. Development activities includes among others: formulation and process-design, control strategy, quality risk management, authoring of development documents and manufacturing instructions for technical and GMP manufacture incl. handling of deviation.

About the Role

Role Responsibilities:

- Lead the development of formulations and manufacturing processes of Drug Products
- Support the development and the qualification of analytical methods together with the AS&T team leader in accordance with ICHs guidelines and internal SOPs. Participate as formulation expert to cross-functional project teams.
- Be accountable for all formulation and manufacturing process deliverables incl. scientific documentation for all assigned projects (Manufacturing instructions, GMP documents, deviation..).
- Guarantee technical support answering DP related questions in inspections and Health Authority requests throughout all phases of the project life cycle.
- Participate to the transfer manufacturing procedures to the relevant department (e.g. Technical Operations, CDMO, etc.).
- Ensure authoring of accurate, comprehensible, structured, complete and legible documents to allow timely start of development trials, process transfers and supply activities.
- Draft the CMC documents required to enable regulatory submissions (IND/IMP, Module3/NDA).
- Provide technical guidance to team members and work according to appropriate SOPs, GLP, GMP, HSE and AdAcAp / Novartis guidelines.
- Proactively communicate key issues and any other critical topic in a timely manner to the appropriate management level, to the TRD DPPL and/or to any other relevant project team member.

Essential Requirements:

- Minimum: PhD in Pharmaceuticals or related sciences with a minimum of 3 years of proven experience within the pharmaceutical/biotech industry or a Master's degree with a minimum of 5 years experience.
- Fluent knowledge of English (oral and written). Desirable knowledge of site language.
- Demonstrated success in developing formulations with an emphasis in liquid sterile dosage forms.
- Technical expertise and detailed understanding of drug product production and control technologies.

- Experience with outsourcing and supervising work done by CRO/CMOs including technical overview of agreement set up.
- Experience in writing CMC documents for regulatory submissions and responding to health authority questions.
- Good basis of Quality Assurance (overall knowledge of GxPs).

Work Experience:

- Functional Breadth.
- Operations Management and Execution.
- Collaborating across boundaries.

Skills:

- Environment.
- Experiments Design.
- Health And Safety (Ehs).
- Laboratory Equipment.
- Manufacturing Process.
- Materials Science.
- Process Simulation.
- Project Management.
- Sop (Standard Operating Procedure).
- Technical Writing.

Languages :

- English.

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

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
[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-10013628

RLT Formulation Project Leader

[Apply to Job](#)

Source URL: <https://www.adacap.com/careers/career-search/job/details/req-10013628-rlt-formulation-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/lvrea/RLT-Formulation-Project-Leader_REQ-10013628
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/lvrea/RLT-Formulation-Project-Leader_REQ-10013628