

RLT Formulation Project Leader

Job ID REQ-10013628

7月 03, 2025

Italy

摘要

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/IMPD, 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 Pharmaceutics 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:

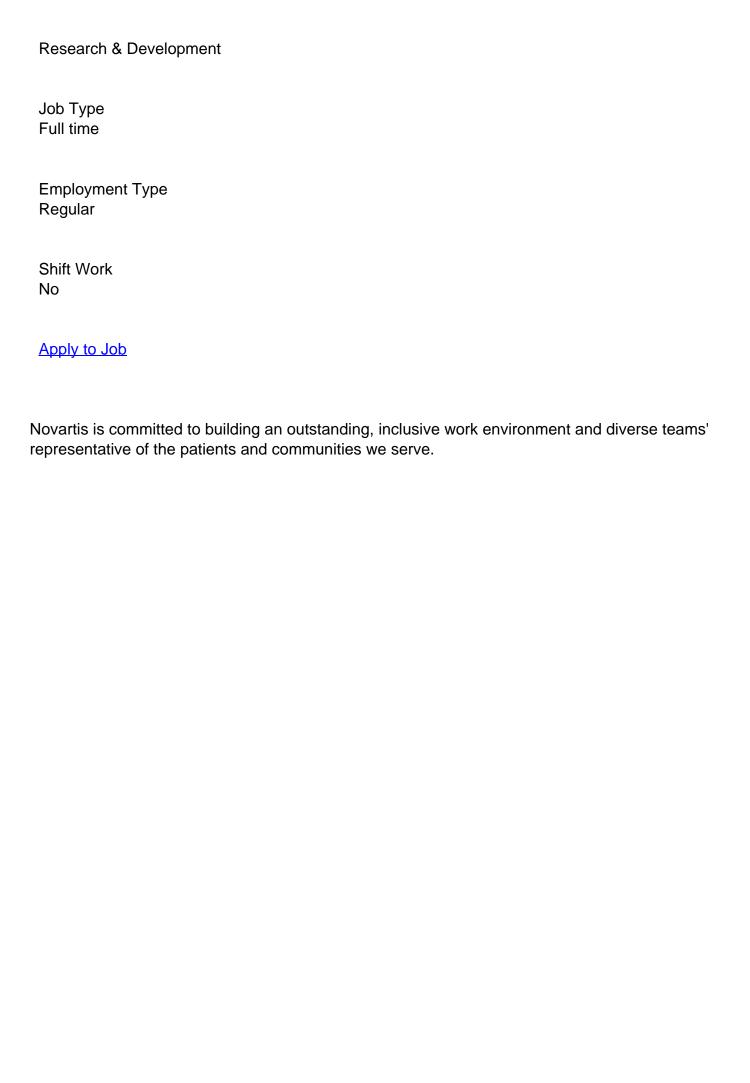
- Functional Breadth.
- Operations Management and Execution.
- Collaborating across boundaries.

Skills:

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

Languages:
• English.
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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
部门 International
Business Unit Development
地点 Italy
站点 Ivrea
Company / Legal Entity IT58 (FCRS = IT058) Advanced Accelerator Applications Italy Srl
Functional Area

• Technical Writing.





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