RLT Formulation Project Leader

Job ID
REQ-10015144

2月 27, 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).

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部门
International

Business Unit
Innovative Medicines

地点
Italy

站点
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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