Drug Product Project Leader - Oral Dosage Forms (80-100%)

Job ID
REQ-10032015

12月 16, 2024

Switzerland

摘要

Location: Basel, Switzerland

Role Purpose:
Novartis holds a rich development portfolio of small molecules ready to develop into innovative, patient centric, oral dosage forms. As a Drug Product Project Leader (DPPL) working on oral dosage forms, you will lead and manage formulation and manufacturing activities linked to pharmaceutical development for small molecules (New Chemical Entities; NCE). For this position, specific emphasis lies on bringing in-depth experience of pharmaceutical unit operations and applying data science tools and mechanistic modelling & simulation to support efficient scale-up and transfer activities.
You will lead drug product teams during all stages of development with a specific focus on late phase clinical phases. You will be working on oral Small Molecules and in particular on enabling formulation approaches. You will use your strong communication, stakeholder management and influencing skills to effectively lead the drug product subteam and the transfer team. Your expertise will facilitate the planning and execution of smart DoE and scale-up / transfer campaigns to establish robust manufacturing processes and stable drug products suitable for human trials and commercial supplies following ICH principles.

About the Role

Your responsibilities will include but are not limited to:

- You lead and manage all Drug Product (DP) related technical development activities for assigned projects and you represent DP project teams in Technical Research and Development (TRD) sub-teams based on your strong scientific and pharmaceutical development expertise.
- You lead, manage and support the DP and the transfer teams in line with Novartis values and behaviors. You build strong team spirit and promote knowledge exchange within and between teams. You motivate and coach team members for high performance.
- You formulate a sound DP project strategy incl. contingency planning and risk assessments as appropriate, involving functional experts, and you ensure alignment with Pharmaceutical Development department and other departments and functions inside and outside of TRD and 3rd parties as appropriate.
- You ensure adherence to the scientific and project review process and through relevant scientific and project management governance boards You ensure creation of high quality and scientifically sound DP development documents enabling a strong CMC submission package, and act as author, reviewer or approver for development documents in accordance with operational procedures and guidelines.
- You contribute to the generation of registration dossiers, answer DP related questions in internal and external audits, and support Health Authority requests.
- You assess, consolidate and negotiate resource needs and timelines for assigned projects within the DP project team and ensure resources are accurately reflected in the planning systems.

What you ' ll bring to the role:

- PhD in Pharmaceutical Sciences or relevant scientific field (e.g., Pharmaceutical Technology, Chemical Engineering).
- 5+ years of relevant technical experience in Development of oral Pharmaceutical Drug Products with proven experience in leading project teams in a matrix organization.
- Successfully demonstrated expertise in pharmaceutical oral dosage form development and manufacturing, i.e. formulations for Small Molecules including enabling formulations, manufacturing and IPC technologies, and scale-up principles.
- An in-depth understanding of material science principles, as applied to oral dosage forms, including the impact of physico-chemical properties of API and excipients on the drug product process and quality.
- Extensive experience with application of Quality by Design and Quality risk management principles and tools as well as a strong working knowledge of regulatory guidelines relevant to Drug Product Development, validation, risk management, testing and stability, as well a new drug applications.
- Experience in applying data science, statistics, and DoE to enhance pharmaceutical development by providing a robust framework for data analysis, experimental design, and decision-making, leading to more effective and efficient drug development processes and documentation.
- Strong knowledge of laboratory and/or technical tools and pharmaceutical manufacturing

technologies, as well as knowledge of relevant GLP, GMP regulations and policies.
- Strong presentation 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.

Accessibility and accommodation
Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to inclusion.switzerland@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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

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部门
Development

Business Unit
Innovative Medicines

地点
Switzerland

站点
Basel (City)

Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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