U NOVARTIS

Formulation Project Leader – Oral Dosage Forms (80-100%)

Job ID REQ-10048565 May 08, 2025 Switzerland

Summary

Location: Basel, Switzerland

Role Purpose:

As a Formulation Project Leader in Oral Late Phase Development (NCE), you will lead and manage formulation and process development of Oral solid dosage forms from Lab-scale through scale-up and transfer to commercial scale in close collaboration with the Drug Product Subteam. Development activities include among others: formulation and process design and optimization, quality risk management as well as scientific writing of development documents and GMP documentation. For this position, special emphasis lies in bringing a keen interest and experience in applied data science and mechanistic modelling as tools to enable data-driven and efficient process development and scale-up.

About the Role

Your responsibilities will include but are not limited to:

- You have a passion for innovative formulations and technologies and bring experience in enabling formulation development.
- You understand the value and ideally bring experience of applying data-centric, computational models to guide formulation and manufacturing process development.
- You drive with scientific excellence the formulation development and manufacturing work of standard and enabling formulations and manufacturing processes of Oral Drug Products (NCE), supported by datadriven conclusions and mechanistic modelling.
- You collaborate closely with the Drug Product Sub-Team and Transfer Team members and together identify, understand and manage critical aspects concerning Drug Substance, Drug Product, Analytics, Packaging and Device.
- You maintain a regular exchange with key experts in e.g., Technology Focus Groups, Modelling & Simulation, Biopharmaceutics and further networks, and build their guidance into the development strategy and project plans.
- You author sound scientific and well-structured development documents as well as GMP documents to enable commercial manufacturing of new Drug Products.
- You contribute to the generation of CMC submission dossiers, support and answer Drug Product related questions of Health Authorities and Inspectors.

What you'll bring to the role:

- Advanced degree (minimum PhD) in relevant scientific field (e.g., Pharmaceutical Technology, Chemical Engineering).
- Minimum 2 years of successful industry experience in the development of pharmaceutical formulations.
 Focus: Formulation and process development of standard and enabling formulations for small molecules (NCE) and scale up of manufacturing processes into oral drug products for commercialization.
- Knowledge of data science and data visualization, ideally experience of applying data-centric, computational models to guide formulation and manufacturing process development.
- Interdisciplinary thinking and interest in collaboration with other functions
- Broad and profound understanding of formulation development activities.
- Good knowledge of laboratory and/or technical tools (e.g., QbD, PAT) as well as knowledge of relevant GLP, GMP regulations and policies.
- Successfully demonstrated track record of creativity and problem solving in projects.
- Effective communication, organizational, planning and negotiation skills.
- Scientific and 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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Division Development Business Unit Innovative Medicines Location Switzerland Site 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 <u>Apply to Job</u>

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