# **U** NOVARTIS

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

Job ID REQ-10048565

5月 08, 2025

Switzerland

### 摘要

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 data-driven 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? <u>https://www.novartis.com/about/strategy/people-and-culture</u>

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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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