

Drug Product Project Leader - Biologics Development

Job ID
REQ-10038531

2月 10, 2025

Switzerland

摘要

As Drug Product Project Leader you will be the strategic lead of complex (e.g. new modalities or late stage) Drug Product Development within Biologics projects and be accountable for agreed upon deliverables to the CMC team.

About the Role

- Lead and co-ordinate the global drug product sub-team (functional experts from e.g. Formulation and Process Development, Analytics, Production, Devices or Regulatory) and represent Drug Product Development on the global CMC team.
- 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 scientific sound DP development documents enabling a strong CMC submission package and

act as author, reviewer or approver role for development documents in accordance to the operational procedures and guidelines.

- Author or review regulatory CMC documents, contribute to the generation of filing dossiers, answer DP related questions in inspections and support Health Authority requests.
- Responsible for resource and budget planning of drug product development activities internally and externally. Proactively communicate project strategy and resource demand. Adapt project strategy and prioritize project activities as needed.
- You will lead and manage key scientific initiatives to develop short & long term drug product development strategies for a large NBE pipeline within global drug product development
- You will provide guidance to junior drug product development scientists and project leaders globally ensuring project management and scientific excellence within the organization.
- You will be working in multidisciplinary and international teams, reporting scientific/technical results internally and representing Novartis externally at meetings, giving talks, being part of industry consortiums, publishing papers.

What you ' ll bring to the role:

- Ph.D. in Chemical Engineering, Biochemical Engineering, Pharmaceutical Technology, or equivalent.
- Minimum of 5 years of successful experience in biotech / pharma industry with emphasis on biologics drug product formulation, process development, and manufacturing for early phases.
- Experience in protein analytics, stability prediction, lyophilization, primary packaging development for biologics as well as project acceleration strategies is an advantage.
- Proven track record in resolving technical issues as well as in the successful leadership of strategic innovation projects.
- Excellent scientific leadership skills, interdisciplinary thinking and proven ability to work in cross-functional, international teams.
- Strong project management skills, ability to solve complex problems in a matrix system with excellent communication and negotiation skills
- Strong presentation skills and scientific/technical writing skills.

Location - This role offers hybrid working, requiring 3 days per week on site.

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>

Commitment to Diversity & Inclusion:

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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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