

Senior Drug Product Project Leader (Biologics Development)

Job ID
REQ-10014697
Sep 17, 2024
Schweiz

Zusammenfassung

Location: Basel, Switzerland

Role Purpose:

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 8 years of successful experience in biotech / pharma industry with emphasis on biologics drug product formulation and process development, manufacturing, scale-up, and technology transfer
- Experience in protein analytics, lyophilization, primary packaging development for biologics as well as

BLA / MAA submission 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.

Why Novartis? Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: <https://www.novartis.com/about/strategy/people-and-culture>

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. <https://www.novartis.com/careers/benefits-rewards>

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.

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: <https://talentnetwork.novartis.com/network>

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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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

Abteilung

Development

Business Unit

Innovative Medicines

Ort

Schweiz

Website

Basel (City)
Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG
Functional Area
Research & Development
Job Type
Full time
Employment Type
CDI
Shift Work
No

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