

Technology and Science Lead - Drug Product Development

Job ID REQ-10021590

6月 19, 2025

Switzerland

摘要

As part of the Drug Product Development Scientific Office you will provide strategic and scientific guidance on integrating new Biologics drug product-related technologies (such as new delivery technologies, new formulation approaches, and new development approaches, e.g. modeling approaches) into CMC projects in collaboration with key stakeholders. You will also support CMC teams in compiling dossiers, drive engagement with industry consortia and health authorities to enable new technologies implementation. In addition, you will propose and lead elaborating scientific solutions to development challenges.

About the Role

 Provide strategic and scientific guidance on integrating new Biologics drug product-related technologies (such as new delivery technologies, new formulation approaches, and new development approaches, e.g., modeling approaches) into CMC projects in collaboration with key stakeholders.

- Promote a comprehensive approach to drug product development that focuses on the needs
 of patients and payers while integrating new technologies (pharmaceutical / in-silico)
 in line with Health Authorities expectations.
- Engage in industry consortia to shape regulatory environment and influence Health Authorities.
- Liaise with key stakeholders, including Biomedical Research, Global Program Teams, Devices and Primary Packaging, Regulatory CMC, Quality, and Commercial Manufacturing sites, to encourage them to integrate new technologies into our Biologics product while ensuring their needs for a patient-centric product are met.
- Support / drive interactions with health authorities through participation on briefing packages
- Proactively identify, lead/propose solution-oriented plans to resolve scientific drug product development challenges/barriers.
- Lead innovation programs as needed

Minimum requirements

- 10+ years experience in the biopharmaceutical industry
- Experience in Biologics development, and specifically DP process development, understanding of drug product manufacturing process operations such as mixing, sterile filtration, and aseptic fill/finish.
- Experience in DP manufacturing of sterile dosage forms including frozen, liquid, and lyophilized formulations in vials and pre-filled syringes and other presentations
- Experience in writing regulatory modules including INDs and BLAs
- Relevant experience of developing and implementing strategies of patient-centered science related work
- Deep understanding of regulatory guidance from the FDA and EMA for development of

biologic drug products, knowledge of USP and Ph. Eur. as it relates to biologics development

- Learning agility towards new delivery, DP process and other innovative technologies
- Experience of cross-functional collaboration and leading within a matrix organisation
- Outstanding influencing skills, leading without authority, excellent presentation and communication skills towards different internal and external stakeholders (senior management, health authorities), outstanding ability to deal with ambiguity, combined with demonstrating strong business acumen

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

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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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