

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

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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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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