

Drug Product Technologies Strategy Lead

Job ID
REQ-10021590

9月 20, 2024

Switzerland

摘要

As part of the Drug Product Development Scientific Office you should provide strategic and technical guidance on product design and development in liaison. When you are a part of the Development team, you'll have countless opportunities to develop your career, as you'll be surrounded by people you can learn from and help you reach your full potential.

Our team is seeking a Drug Development Technologies Strategy Lead.

As part of the Drug Product Development Scientific Office you will provide strategic and technical guidance on product design and development in liaison with key stakeholders in CMC, drive engagement with industry consortia and health authorities to enable new technologies implementation, and propose and drive solutions to development challenges.

This role is based in Basel, Switzerland.

About the Role

Your responsibilities include, but are not limited to:

- Champion holistic understanding of patient- and payer focused drug development and incorporate new technologies (pharmaceutical / in-silico) in conjunction with Health Authorities expectations.
- Engage in industry consortia to shape regulatory environment and influence key opinion leaders.
- Liaise with key stakeholders, including Biomedical Research, Global Program Teams, Devices and Primary Packaging, Regulatory CMC, Quality, and Commercial Manufacturing sites, to integrate Drug Product requirements with their needs for a patient-centric product.
- Provide strategic and technical guidance on Drug Product Design and product development strategy
- Support / drive interactions with health authorities through participation on briefing packages
- Proactively identify, lead/propose solution oriented plans to resolve drug product development challenges/barriers.
- Lead scientific programs and act as member of advisory boards for scientific issues

Minimum requirements

- 10+ years experience in the biopharmaceutical industry with a Scientific qualification.
- Prior experience in project leadership or people management paired with the ability to engage cross-functional teams
- Experience of cross-functional collaboration and leading within a matrix?
- Experience in Drug Product manufacturing of sterile dosage forms including frozen, liquid, and lyophilized formulations in vials and pre-filled syringes
- 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.
- Relevant experience of developing and implementing strategies of patient-centered science related work
- Analytical thinking to anticipate impact and consequences
- Experience in writing regulatory modules including INDs and BLAs
- Knowledge 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 technologies

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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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