Formulation Project Leader xRNA Therapeutics - Senior Expert

Job ID
REQ-10059955

8月 19, 2025

Switzerland

摘要

Join our team in Pharmaceutical & Analytical Development (PHAD) and be a part of cutting-edge parenteral drug product development. Contribute to the advancement of novel technology platforms such as Oligonucleotides, and work on the Novartis main Campus in Basel. This is your chance to make a significant impact in the biopharmaceutical field and be at the forefront of bringing life-changing medicines to patients worldwide. The PHAD specialty Unit is seeking an experienced Formulation Drug Product Project Leader (FPL) to lead drug product formulation and manufacturing process development. Apply now and be a part of a team that is revolutionizing drug product development.

About the Role

Major accountabilities:

- Be accountable for all formulation and manufacturing process deliverables including scientific

documentation, design of experiments of parenteral products, batch records, deviations, change controls, CAPAs, tech transfer, and reports.
- Drive DP development, manufacturing process transfers and supply activities with scientific and technological excellence
- Work closely with cross functional teams both internal and external to provide technical input for the development and manufacturing process (including CRO and CMOs).
- Provide technical support to compile technical regulatory documentation and responses to regulatory agencies as needed.
- Assist with writing and reviewing of CMC documentation associated with project or manufacturing changes.

Key Skills

- **Formulation Expertise:** Experience developing injectable drugs, including solutions, suspensions, and aseptic formulations. Knowledge of RNA-based therapies (e.g., siRNA, mRNA) and drug delivery systems like pre-filled syringes or vials.
- **Process Development**: Skills in designing manufacturing processes and transferring them to production environments. Familiarity with aseptic drug manufacturing and methods like QbD.
- **Regulatory Knowledge:** Understanding of GMP and preparing technical documentation for regulatory submissions.
- **Analytical Thinking:** Designing experiments (e.g., DoE) and analyzing data to improve formulations and manufacturing processes.
- **Collaboration & Communication:** Strong teamwork skills for working with internal teams and external partners (e.g., CROs/CMOs). Clear communication and ability to write reports, technical documents, and regulatory responses.
- **Problem-Solving:** Ability to handle deviations, implement corrective actions, and improve manufacturing processes.
- **Innovation:** Interest in advancing RNA drug delivery platforms and contributing new ideas to the field.

Preferred Technical Experience

- Working knowledge of oligonucleotide-based therapies (e.g., ADCs, proteins, RNA-based drugs).
- Familiarity with process development for clinical-grade parenteral drug products. Proven experience in related fields such as pharmaceuticals, biotechnological product development, and advanced drug delivery platforms.

Required Qualifications:

- **Ph.D., Master's or Bachelor's Degree in Chemistry or related disciplines.** With **2+ years** (Ph.D.), **5+ years** (Master's), or **8+ years** (Bachelor's) biopharmaceutical experience.
- Proven expertise in formulation and manufacturing process development for parenteral and aseptic products.

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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