

Drug Product Project Leader - Parenterals (m/f/d)

Job ID
REQ-10013083
Sep 27, 2024
Switzerland

Summary

Location: Basel, Switzerland

Role Purpose:

Join our team in Pharmaceutical Development (PHAD) and be a part of cutting-edge parenteral drug product development. Contribute to the advancement of novel technology platforms such as Radioligand Therapies (RLTs) and 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 Drug Product Project Leader (DPPL) to lead DP development sub-teams, be accountable for the DP development project strategy and represent DP development in the global CMC project team! Apply now and be a part of a team that is revolutionizing drug product development.

About the Role

Responsibilities

- As Drug Product Project Leader be the strategic lead of complex Drug Product Development projects (e.g. for Oligonucleotides or RLTs) within the PHAD Specialty Unit
- Lead and manage all formulation and process development activities for parenteral formulation development and parenteral manufacturing.
- Represent DP project teams in global CMC teams, providing strong quality awareness, scientific expertise, and project management skills.
- Develop a sound DP project strategy, including contingency planning and risk assessments, in line with overall Technical R&D project plan and guidelines.
- Monitor project plans and ensures timely availability of agreed timelines.
- Contribute actively to network deliverables and cross-functional initiatives, promoting collaboration and knowledge sharing.
- Act as an author, reviewer, or approver for PHAD owned documents, supporting submission writing and addressing inspection requirements.
- Ensures adherence to the EP/ LP project review process and high quality documentation through relevant governance boards.
- Leads the Transfer Team and clinical development activities in alignment with TDP for late phase and LCM projects.
- Leads and / or contributes actively to respective Network deliverables and cross-functional workstreams/initiatives.
- Assesses, consolidates and negotiates resource needs (internal & external costs) and timelines. Lead

budgeting process for DP activities.

Requirements

- Ph.D. in Chemistry, Chemical Engineering, Pharmaceutical Technology or related disciplines with 7+ years of industry experience in parenteral drug product development, e.g. for Oligonucleotides (mRNA, siRNA, ASO) or Biologics (ADC, proteins), OR Master's degree with 9+ years of biopharmaceutical industry experience.
- Broad and profound understanding of development activities and processes in pharmaceutical sciences (parenteral, aseptic, solution, and/or suspension)
- Strong knowledge of laboratory and/or technical tools ((e.g., Quality by Design, statistical software, Process Analytical Technology).
- Familiarity with devices such as pre-filling syringes, vials, and combination products is an advantage.
- Strong scientific leadership skills.
- Basic / Advanced skills in Data Analysis and Data Visualization, including application of data science tools
- Strong knowledge of relevant GLP, GMP regulations and policies requirements in parenteral Drug Product development and manufacturing.

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>

Division

Development

Business Unit

Innovative Medicines

Location

Switzerland

Site

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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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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