

Analytical Expert (ARD) (m/f/d)

Job ID
REQ-10032019

12月 16, 2024

Switzerland

摘要

Location: Basel, Switzerland

Role Purpose:

We are searching for an Analytical Expert to support Analytical Research & Development (ARD) in the area of Project management. ARD sits within the Technical R&D department of Development and plays an essential role in the characterization and analysis of Drug Substances and Drug Products from the time they leave the discovery laboratory until they are transferred to Commercial Production. We are looking for a highly motivated and experienced Analytical Expert with experience in Oligonucleotide analytics.

About the Role

Major accountabilities:

- You will help leading analytical activities within a Technical CMC project team (e.g., help to define control and specification setting strategies for Drug substances and Drug products, method development, validation, stability, and release testing)
- You provide valuable input to the analytical CMC documents and support regulatory submissions.
- Manage interactions and contribute to a high level of collaboration with internal and external stakeholders.
- Write of analytical source documents (e.g Analytical methods, Specifications, Validation reports, Stability reports)
- Lead outsourced analytical activities at CROs / CDMOs and contribute to manage the external partnership.
- You will be responsible to evaluate and implement new analytical methodologies with the aim of bringing the lab at the forefront of Oligonucleotide analytics.
- You will be responsible for writing and reviewing analytical documentations with a high focus on quality, data integrity and timelines.
- You will drive, lead, and manage analytical activities including impurity profiling related to the analytical development of Oligonucleotides (e. g. method development, validation, stability, and release testing).
- Provide scientific guidance to the cross-functional and global project teams and thereby scientifically driving our exciting Oligonucleotide portfolio.
- Display a collaborative and inspired attitude within the Oligonucleotide lab, project teams and stakeholders is key.

What you ' ll bring to the role:

- Desirable: PhD in analytical chemistry or equivalent and a minimum 3 years ' experience in the pharmaceutical industry in analytical development, preferably in development of sterile parenteral products. Strong expertise in the field of oligonucleotide analytics.
- Profound knowledge in analytical separation techniques such as liquid chromatography (RP, IEX and HILIC) is a must. Experience in method development and troubleshooting. Experience in developing control strategies.
- Profound expertise in Mass Spectrometry (ranging from mass confirmation to actual quantitative analysis of impurities and sequencing) is a plus.
- Proven leadership in guiding and mentoring colleagues
- GMP experience and qualification expertise in a GMP environment are assets.
- Strong coordination skills, collaborative spirit, self-driven attitude, high level of learning agility are key attitudes
- Strong quality focus
- Eager to develop new methods and assess new analytical techniques.
- High level of intrinsic motivation, excellent collaborative spirit and agility are key elements for our success.
- Analyse and interpret complex situations, provide detailed directions for analytical approaches

Languages :

- English

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.

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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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