

Analytical Expert - ARD (m/f/d)

Job ID
REQ-10047459

4月 04, 2025

Switzerland

摘要

Location: Basel, Switzerland

Role Purpose:

We are looking for an Analytical Expert to support Analytical Research & Development (ARD). ARD sits within the Global Technical R&D department of Global Drug Development and plays an essential role in the characterization and analysis of Small Molecule 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, experienced Analytical Expert with a strong background and experience in parenteral development to join our team.

Expertise in RLT, peptide analytics and parenteral dosage form is required.

About the Role

Your main responsibilities:

- Plan, interpret and report results of scientific experiments for timely supply of drug substances (DS) and drug products (DP).
- Write & review analytical documents (e.g Analytical methods, Specifications, Validation reports, Stability reports, Batch records for stability and release testing) and align the corresponding activities within a global project team.
- Drive method development for peptide drug substances and RLT Drug product.
- Manage interactions with internal and external stakeholders, including outsourced activities to CROs by providing scientific and technical guidance whenever necessary.
- Proactively identify scientific, technological and GMP challenges, propose creative solutions and communicate key issues to the Analytical Project Leader or respective technical project team.
- Work according to appropriate SOPs, GMP, Quality Directives, Health and Safety & internal Novartis guidelines.
- Provide valuable input to the analytical CMC documents and support regulatory submissions.
- Drive, lead, and manage analytical activities including impurity profiling related to the analytical development of RLTs compounds (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 RLT portfolio.
- Display a collaborative and inspired attitude within project teams and our stakeholders and partners is key.
- Good understanding and awareness of regulatory guidelines for analytical development

What you ' ll bring to the role

- PhD in analytical chemistry or equivalent
- At least 5 years experience in the pharmaceutical industry with a track record in GMP activities for development or marketed products.
- Profound expertise in documentation writing (Stability Report, Validation, IND IMPD modules etc)
- Broad scientific knowledge in chemistry, pharmaceutical or analytical sciences, ability to perform in a highly dynamic environment.
- Advanced knowledge of laboratory and/or technical tools (e.g. HPLC, LC-MS, Quality management systems, statistical evaluation tools ...)
- Good knowledge of commonly used software and computer tools.
- Excellent scientific/technical writing skills.
- Eager to develop new methods and assess new analytical techniques.
- Proven leadership in guiding and mentoring colleagues
- Strong coordination skills, collaborative spirit, self-driven attitude, high level of learning agility.
- Strong quality focus
- Excellent communication and role model skills
- Fluent in English (oral and writing)

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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