

Associate Director - Analytical Project Lead Medical Devices (m/f/d)

Job ID
REQ-10088101
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Австрия

Сводка

With the increasing diversity of Novartis' portfolio, the need for drug-device combination product analytical data packages is also increasing. As such, we are searching for a Senior Expert - Medical Device Analytical Representative with combination product development experience to lead the creation of strong analytical data-packages. As a member of the global Chemistry Manufacturing Control (CMC) analytical sub team and device sub team for your project(s) you will be the main contact & coordinator for all project-specific analytical tasks related to functional attributes of drug-device combination products at all levels (from component to drug product to final product), especially for injectables like Biologics, Ribonucleic Acids, Radio-Ligands (peptides) in e.g. a prefilled syringe in a autoinjector or needle-safety-device.

#LI-Hybrid
Location - Schaffnau, Austria

About the Role

Key Responsibilities:

- As a member of global CMC analytical subteam and device subteam for your project(s), you are the contact person & coordinator for all project-specific analytical tasks related to functional/mechanical attributes of drug-device combination products at all levels (from component to drug product to final product); plan resource & budget for your project(s).
- Select testing laboratory inline with resource availability, capability and in/outsourcing strategy, e.g. GDPD, QC, CRO; lead outsourced analytical project activities at CROs and contribute to manage external partnership.
- Own drug-specific analytical methods (AMs) / parameter sheets (PSs) for functional attributes like activation and injection force, time, volume, sound, as well as (needle) safety features, organize and align x-functional inputs (e.g. with Device/Pack Tech); define, organize, document AM/PS validation and transfer.
- Co-shape and co-author x-functional analytical CMC strategies and documents, e.g. drug product and final product stability strategy, protocols and reports, method validation and transfer status summaries, Analytical Specifications (AS); organize input to Justification of Specification JoS (from Device/PackTech and HFE).
- Contribute to and review regulatory documents, support product registrations with a minimal support by Leader or assigned to moderately complex projects.
- Performs statistical data analysis using statistical tools (e.g. Minitab) to generate and justify device related specifications for clinical and commercial setup.

Essential Requirements:

- Master or PhD in engineering or chemical/bio analytics or equivalent and minimum 5 years' experience and strong knowledge in (parenteral) Combination Product Development or related area (e.g. Manufacturing, Regulatory, QA)
- Proven knowledge in late phase parenteral analytical development; leadership experience in managing development projects, ideally in a global matrix environment, understanding and awareness of regulatory guidelines for combination. product analytics, experience with cGMP and relevant ISOs
- Collaborative spirit, self-driven attitude, high level of learning agility.
- Proficiency in English (written and spoken).

Rewards:

In addition to a market-competitive base salary, we offer an attractive incentive program, a modern company pension scheme, childcare facilities, learning and development opportunities as well as worldwide career possibilities within the Novartis group. In accordance with Austrian law, we are obliged to disclose the minimum salary as stated in the collective bargaining agreement. For this position the minimum salary is € 78,383.90 EUR/year (on a full-time basis). The actual salary will be significantly higher, as we strive to maintain a competitive position in the market and consider your previous experience, qualifications and individual competencies.

We are open for part-time and job-sharing models and support flexible and remote working where possible.

Commitment to Diversity and Inclusion / EEO paragraph:

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

Adjustments for Applicants with Disabilities:

If because of a medical condition, physical disability or a neurodiverse condition you require an adjustment during the recruitment process, please reach out to disabilities.austria@novartis.com and let us know the nature of your request as well as your contact information. The support which we can provide will include advice on suitable positions as well as guidance at all stages of the application process. Austrian law provides candidates the opportunity to involve the local disability

representative, Behindertenvertrauensperson (BVP), in the application process. If you would like to request this, please let us know in advance as a note on your CV.

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>

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
[Read our handbook \(PDF 30 MB\)](#)

Primary location salary range

€88,300.00 - €164,100.00

Дивизион

Development

Business Unit

Development

Место

Австрия

Сайт

Schaftenau

Company / Legal Entity

AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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2. <https://www.novartis.com/about/strategy/people-and-culture>

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