NOVARTIS

Senior Project Mgr (Ass. Director) - Drug Device Combination Product Analytics f/m/d

Job ID
REQ-10009566
Aug 29, 2024
Austria

Summary

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 / Project Manager 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).

About the Role

Major accountabilities:

Your responsibilities include but are not limited to:
• Leading all analytical tasks of complex projects incl. planning resource & budget and authoring respective analytical documents.

• Selecting testing laboratories in line with resource availability, capability and in/outsourcing strategy; these include the laboratories of Novartis Global Device & Packaging Development (GDPD), as well as Novartis TechOps Quality Control and external Contract Research Organisations (CROs).

• Leading outsourced analytical project activities at CROs and contributing to the management of external partnerships.
• Taking ownership of drug-specific analytical methods (AMs) / parameter sheets (PSs) and organising and aligning x-functional inputs (e.g. with Device/Pack Tech).

• Defining, organising and documenting AM/PS validation and transfer.
• Co-shaping and co-authoring x-functional analytical CMC strategies and documents; This will include drug product and final product stability strategy, protocols and reports, method validation and transfer status summaries and Analytical Specifications (AS).

• Organizing and aligning input to Justification of Specification (JoS) from Device/PackTech and Human Factors Engineering (HFE)

• Leading x-functional overarching initiatives; mentoring (senior) experts
• Contributing to and reviewing regulatory documents, supporting product registrations and presenting at

inspections.

Minimum Requirements:

• Master or PhD in engineering or functional/chemical/bio analytics or equivalent and minimum 10 years' experience in pharmaceutical industry, including drug-device combination product development
• Profound knowledge in analytical tasks including functional (physical) testing of late phase parenteral drug delivery devices or combination products

• Leadership experience in managing development projects, ideally in a global matrix environment.

• Understanding and awareness of regulatory guidelines for combination product analytics.

• Experience with current good manufacturing practice (cGMP) and relevant ISOs.
• Collaborative spirit, self-driven attitude, high level of learning agility
• Fluent in English (oral and writing)

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: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-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. Level 5: 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 € 89,600.00/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.

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.

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Division
Development
Business Unit
Innovative Medicines
Location
Austria
Site
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
Apply to Job

Adjustments for Applicants with Disabilities

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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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