Project Manager – Drug Device Combination Product Analytics (f/m/d)

Job ID
394730BR
Jul 01, 2024
Austria

Summary

Location: Schaftenau, Austria, Type: Hybrid Working #LI-Hybrid 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.

About the Role

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). This will include planning resource & budgeting for your project(s) and authoring respective analytical documents.

Key Responsibilities:

Your responsibilities include but are not limited to:

• Selecting testing laboratories in line with resource availability, capability and in/outsourcing strategy; This will include the laboratory of Global Device & Packaging Development (GDPD), Quality Control and 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 input to Justification of Specification (JoS) from Device/PackTech and Human Factors Engineering (HFE)

• Contributing to and reviewing regulatory documents, supporting product registrations and presenting at

inspections.

Essential Requirements:

• Master or PhD in engineering or functional/chemical/bio analytics or equivalent and minimum 5 years' experience in pharmaceutical industry in combination product development

• 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 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?

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

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 € 71,028.44/year (on a full-time basis). In most cases, the actual salary will be 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 & Inclusion:

Novartis is committed to building an outstanding, inclusive working 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.

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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Innovative Medicines
Location
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Site
Schaftenau
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