

Group Head – Associate Director Risk Mgmt Drug Device Combination Products (f/m/d)

Job ID
REQ-10013855
Jul 01, 2024
Austria

Summary

Location: Schafftenau, Austria, Type: Hybrid Working #LI-Hybrid With the increasing diversity of Novartis' portfolio, the need for understanding and managing technical and user risks and defining sound control strategies securing the quality of drug-device combination products is also increasing. As such, we are searching for a Group Head / Associate Director with risk management, combination product development and people management experience to lead the team and build the strategies.

About the Role

As leader of your team of experts and as member of the competence center lead team you ensure that all risk management and control strategy related activities are delivered for Novartis' drug delivery device and drug-delivery combination product development portfolio. You will also drive respective global strategy for Novartis.

Key Responsibilities:

Your responsibilities include but are not limited to:

- Leading a team of experts you ensure that technical (design and manufacturing) and use-related risks are identified, assessed and mitigated for the Novartis' device and combination product development portfolio of Biopharmaceutical, RNA, small molecule, radioligand, cell & gene therapy drugs.
- You ensure state-of-the-art and harmonised control strategies securing product quality, e.g. testing / not testing at various product stages and the justification, which are understood and accepted by Health Authorities and are inline with QbD (Quality by Design) approaches like ICH Q12.
- This requires strong collaboration within GDPD organisation (Global Device & Packaging Development, Device & Packaging Technology and Human Factors Engineering) and with partners like Technical Operations, Clinical Development, Drug Development.
- You develop and support your team for best possible performance short- and long-term, you support your team in challenging projects and for strategic presentations as needed.
- You drive further development of high-quality efficient and effective approaches and processes for risk management and control strategy, inline with Novartis and external requirements, at the forefront of / shaping future approaches.
- You act proactively in building the culture to enable high employee engagement; seek for diversity and a high performing, supportive team • You contribute to and review regulatory documents, supporting product

registrations and presenting at inspections.

Essential Requirements:

- Master or PhD in engineering or pharmaceutical field or equivalent and minimum 8 years' experience in pharmaceutical industry in technical combination product development.
- Leadership experience in leading people and/or global projects.
- Proven knowledge in risk management and control strategy
- Understanding and awareness of regulatory guidelines for combination products, including relevant ISOs and current good manufacturing practices (cGMP). • Collaborative spirit, self-driven attitude, high level of learning agility, listener, strategic, interested in people development. • 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 €95,271.68/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>

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up:

<https://talentnetwork.novartis.com/network>

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

Regulär

Shift Work

No

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Unterstützungen für BewerberInnen mit Behinderungen

Wenn Sie aufgrund einer Erkrankung, einer körperlichen Behinderung oder eines neurodiversen Zustandes eine Unterstützung bei verschiedenen Teilen des Rekrutierungsprozesses benötigen, wenden Sie sich bitte an disabilities.austria@novartis.com und teilen Sie uns die Art Ihrer Anfrage sowie Ihre Kontaktinformationen mit. Unsere Unterstützung umfasst die Beratung zu geeigneten Positionen sowie die Begleitung bei allen Phasen des Bewerbungsprozesses. Das österreichische Gesetz sieht die Möglichkeit vor, die örtliche Behindertenvertrauensperson (BVP) in das Bewerbungsverfahren einzubeziehen. Wenn Sie dies wünschen, teilen Sie uns dies bitte vorab als Vermerk in Ihrem Lebenslauf mit.

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2. <https://talentnetwork.novartis.com/network>
3. https://novartis.wd3.myworkdayjobs.com/de-DE/Novartis_Careers/job/Schaftenau/Group-Head---Associate-Director-Risk-Mgmt-Drug-Device-Combination-Products--f-m-d-_REQ-10013855
4. <mailto:disabilities.austria@novartis.com>
5. https://novartis.wd3.myworkdayjobs.com/de-DE/Novartis_Careers/job/Schaftenau/Group-Head---Associate-Director-Risk-Mgmt-Drug-Device-Combination-Products--f-m-d-_REQ-10013855