NOVARTIS

Senior Expert Risk Management & Control Strategy

Job ID
REQ-10075619
апр 17, 2026
Австрия

Сводка

Location: Schaftenau, Austria #onsite

Role Purpose:
With the increasing diversity and complexity of Novartis' drug delivery device and drug–device combination product portfolio, robust and harmonized risk management and control strategies are critical to ensure patient safety, regulatory compliance, and sustainable product quality.

As Senior Expert Risk Management & Control Strategy, you will act as a technical and strategic authority within the RMCS team, shaping how risks are identified, assessed, controlled, and documented across the device development lifecycle. You will work at the interface of design, quality, regulatory, manufacturing, and suppliers, enabling defendable decisions and fit-for-purpose control strategies for global development programs.

About the Role

Key responsibilities:

- Act as **senior subject matter expert** for device and combination product risk management in accordance with ISO 14971, MDR, FDA expectations, and Novartis internal standards.
- Define, assess, and challenge **technical/design, manufacturing, and use-related risks**, ensuring risks are adequately mitigated and justified.
- Develop and strengthen **control strategies** (e.g. testing vs. not testing, process controls, verification strategies) across development and lifecycle stages.
- Drive **consistency and quality** of Risk Management Files (RMF), Risk Management Plans, and Risk Management Reports across projects and platforms.
- Provide expert guidance to project teams on **risk acceptability, residual risk justification, and benefit–risk considerations**
- Support **health authority submissions and interactions**, including inspection readiness and responses related to risk management and control strategy.
- Contribute to methodologies, templates, guidance documents, and training materials.
- Coach and mentor junior experts and project team members, strengthening risk management capability and culture across the organization.
- Proactively engage stakeholders to **pre-align on risk positions** and avoid late-stage surprises.

Essential Requirements:

- Advanced degree in engineering, life sciences, or a related technical discipline.
- Extensive hands-on experience in **medical device and/or drug–device combination product risk management**
- Strong working knowledge of **ISO 14971**, EU MDR, FDA device expectations, and Quality-by-Design principles.
- Proven ability to translate complex technical risks into **clear, defendable, and regulator-ready documentation**.
- Track record of influencing cross-functional stakeholders without direct authority.
- Structured, analytical mindset with strong judgment and decision-making capability.

Desirable:

- Experience across multiple device platforms (e.g. autoinjectors, inhalers, pumps).
- Exposure to **combination products** within pharmaceutical development.
- Experience supporting regulatory submissions, audits, or inspections.
- Ability to act as a reference point for best practices and emerging regulatory trends.

Languages :

- English
- German

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 €65,604.54/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

Austria 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)

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

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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