NOVARTIS

Senior Expert Risk Management & Control Strategy

Job ID
REQ-10075619
Apr 17, 2026
LOC_AT

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.

Role Requirements

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)

Division
DIV_GD
Business Unit
Development
Location
LOC_AT
Site
Schaftenau
Company / Legal Entity
AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH
Functional Area
FCT_RD
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

Job ID
REQ-10075619

Senior Expert Risk Management & Control Strategy

Apply to Job

Source URL: *https://prod1.jobapi.novartis.com.cn/req-10075619-senior-expert-risk-management-control-strategy*

List of links present in page

1. https://prod1.jobapi.novartis.com.cn/req-10075619-senior-expert-risk-management-control-strategy
2. mailto:disabilities.austria@novartis.com
3. https://www.novartis.com/about/strategy/people-and-culture
4. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Schaftenau/Senior-Expert-Risk-Management---Control-Strategy_REQ-10075619
6. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Schaftenau/Senior-Expert-Risk-Management---Control-Strategy_REQ-10075619