

# Regulatory Affairs Medical Device Manager (Schaftenau, Austria)

Job ID

REQ-10011610

Jun 28, 2024

Austria

## Summary

Our Development Team is guided by our purpose: to reimagine medicine to improve and extend people's lives.

To do this, we are optimizing and strengthening our processes and ways of working. We are investing in new technologies and building specific therapeutic area and platform depth and capabilities – all to bring our medicines to patients even faster. We are seeking key talent, like you, to join us and help give people with disease and their families a brighter future to look forward to. Apply today and welcome to where we thrive together! The Role: This role will be based at the Novartis Schafftenau site in the Tyrol, Austria. As Global Program Regulatory Manager Medical Devices & Drug/Device Combination Products you will independently provide strategic and operational global medical device regulatory direction and documentation for projects/products. This includes those projects/ products in development, registration and approval/post approval. You will make informed regulatory decisions, balancing patient and business risks and benefits leading to timely Health Authority approvals.

## About the Role

### Major accountabilities:

- You will support the global Medical Device & Precision Medicine regulatory strategy with a focus on innovation, maximizing business benefit balanced with regulatory compliance.
- Lead, support and implement all global Regulatory Affairs Medical Device (RA MD) submission activities for assigned projects/products, identifying the required documentation for timely global submissions to deadline.
- Author and/or review high-quality RA MD documentation for HA submission, applying agreed RA MD Global regulatory strategies, current regulatory trends and guidelines.
- Proactively communicate RA MD regulatory strategies, risks and key issues throughout the life cycle, to project teams and other stake holders. Represent department in cross-functional project teams as appropriate.
- Lead, prepare and communicate RA MD Risk Management Assessments, contingency plans, and lessons learned on major submissions and escalate as appropriate.
- Initiate and lead Health Authority interactions and negotiations as appropriate; setting objectives, preparing briefing books, coordinating and planning rehearsals and risk mitigation plans.

- Establish and maintain a single point of contact with global HAs.
- Represent department on due diligence teams for in-licensing and divestment opportunities.

### **Your Experience:**

- Science Degree (e.g. Chemistry, Pharmacy, Biochemistry, Biotechnology, Biology) or equivalent
- Medical device & Drug/Device Combination Products regulatory affairs experience, in the pharmaceutical and/or medical device industry.
- Good knowledge and experience in medical device & Drug/Device Combination Products regulatory submissions and approval processes, with understanding of product development life cycle.
- Ability to critically evaluate data from a variety of sources, work in interdisciplinary teams and prioritise activities, timelines and workload.
- Strong interpersonal skills and experience working in a complex, cross functional organization.
- Fluency in English.

**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>

### **Commitment to Diversity & Inclusion:**

Novartis is committed to building an outstanding, inclusive work environment and diverse team's representative of the patients and communities we serve.

### **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>

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Business Unit  
Innovative Medicines  
Location  
Austria  
Site  
Schafftenau  
Company / Legal Entity  
AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH  
Functional Area  
Research & Development  
Job Type  
Full time  
Employment Type  
Regular  
Shift Work  
No  
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REQ-10011610

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