

Senior Expert Engineering - Pilot Plant Drug-Device Combination Products (m/f/d)

Job ID
REQ-10050127

5月 05, 2025

Austria

摘要

The Global Device and Packaging Department (GDPD) is launching its first GMP manufacturing plant for the assembly of combination products at the Novartis Campus in Schafftenau. Starting from 2026, the GDPD Pilot Plant will assemble pre-filled syringes into different types of medical devices and become a key player in the supply of world-wide clinical trials. We are currently looking to build a motivated and talented team, with an interest to set up and maintain all processes required to make a combination product and to prepare the plant for its first batch and beyond. Are you ready to be part of something new?

About the Role

Key responsibilities:

- Take over responsibility for general tasks within the building (gowning, cleaning, HSE).
- Responsible for setting up, organizing and maintaining the paper archive.
- Prepare, own and update production SOPs (e.g. operational manuals, operational processes, IPC) and MBRs for the Pilot Plant production.
- Act as SPOC for the production equipment (e.g. assembly and packaging lines) and provide technical and scientific insights for process-specific issues to ensure compliant and timely execution of processes. Train and support the manufacturing team during batch production. Provide oversight during manufacturing, if required.
- Lead, develop and implement technical solutions for new manufacturing processes and products at the pilot plant.
- Responsible for line and process qualifications respecting deadlines and current regulations and GMP requirements, including periodic requalification.
- Represent and act as a single point of contact for the pilot plant in cross-functional project sub-meetings for product transfers (into GDPD Pilot Plant and from Pilot Plant to Novartis Operations).
- Support in HSE investigations and ensure timely mitigation actions.
- Lead Root Cause Investigations for production deviations using investigation tools and methodology.
- Prepare, support and follow-up of Health authority and internal inspections.

Essential Requirements:

- Master or PhD degree in Engineering, Chemistry, Pharmaceutical Science or another Scientific discipline.
- Minimum 5 years ' experience in drug-device combination product technical development and/or Technical Operations, with knowledge in qualification processes.
- Good understanding of current GMP practice and experience in scientific and technical writing (e.g. SOPs) as well as change and investigation management is a must.
- Proven ability to independently manage tasks and projects on time and addressing challenges proactively with a problem-solving attitude.
- Experience in internal and external stakeholder management and effectively communicate in dynamic cross-functional teams.
- Willingness to build up and integrate into a new, supportive and flexible team with a hands-on mentality.
- Fluent in English, German is an advantage.

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/peopleandculture>

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 € 60.212,18 a 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.

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>

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

部门
Development

Business Unit
Innovative Medicines

地点
Austria

站点
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

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