

Validation Lead

Job ID
REQ-10024277
Oct 03, 2024
Austria

Summary

Our competence center in Schafftenau for state-of-the-art cell culture technology, specializing in the development and production of innovative biologics and biosimilars. Production of thyroid hormones, growth hormones and growth inhibitors.

About the Role

- Responsible and supporting validation activities at Drug Product Schafftenau, i.e. for filling & compounding processes, primary packaging activities (assembly & packaging), cleaning validation
- Support revalidation strategies to meet cGMP and quality requirements on time and on budget to ensure that programs are compliant with Regulatory Authorities' expectations and related SOPs.
- HT verifications, general verification studies
- Support establishing local procedures & templates for validation activities and contribute to improvements and optimization of concepts/strategies etc
- Providing senior expertise on complex process validation topics
- Presence and support of Health Authorities, internal and customer inspections

Minimum Requirements:

- Min 2-3 years of relevant experience in pharmaceutical manufacturing, tech transfer management / manufacturing science and technology / technical development / quality / validation
- University degree (MSc. or PhD) in Biology, Biochemistry, Biotechnology, Biochemical Engineering, or equivalent experience
- Solid understanding / insights into DP production (aseptic filling) and/or assembly & packaging activities and respective validation activities
- Basic experience in Project Management, good organization and planning skills
- Understanding and oversight of relevant regulatory requirements, e.g. GMPs, ICH Q-guidelines.
- Problem-solving and idea generation skills to apply smart risk management and decision-making strategies
- Excellent relationship / external stakeholder management skills
- Ability to work in a matrix organization
- Excellent written and verbal communication/presentation skills
- Fluent in English, German desirable

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 € 64.023/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.

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>

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>

Division
Operations

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