

QA Operations Expert

Job ID
393585BR
Aoû 15, 2024
Autriche

Résumé

In 2014 the first medical device was introduced to the market by Novartis/Sandoz, since then the portfolio for medical devices and combination products are heavily growing. Be part of the QA Medical device team and support commercialization of new devices to the markets worldwide. As part of our team, you will be supporting introduction of new autoinjector devices to commercial phase and manage the device suppliers from a quality point of view. You will be responsible for managing quality aspects within area of responsibility and to ensure that the operational business is in compliance with cGMP (Current Good Manufacturing Practices), the Quality Assurance Agreement, regulatory requirements & the Novartis Quality Manual and is conducted according to the relevant Standard Operating Procedures.

About the Role

Key Responsibilities:

Your responsibilities include, but are not limited to:

- Oversight of all production & testing activities, ensuring compliance with cGxP, incl. data integrity and eCompliance
- Support exception investigations
- Review and approve of production, QC, and AS&T records
- MBR review
- Support OpEx improvement projects
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt
- Distribution of marketing samples (where applicable)
- Responsible for third party management of device component and primary packaging material suppliers
- Review and approval of DHF and DMR documents for Commercial medical devices and combination products

Essential Requirements:

- University degree in Engineering, Pharmacy, Biochemistry, Biotechnology, Chemistry, Microbiology or equivalent
- At least 3 years or more experience in MS&T, QC or QA or medical device industry
- Experience in operations management and execution
- Preferably experience in negotiations and global collaboration
- Fluent knowledge of English language (written and spoken), German is an advantage
- Flexibility to work in a fast paced, quickly changing work environment

- Ability to operate in a global matrix environment

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 € 60.600 /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

Emplacement

Autriche

Site

Schaftenau

Company / Legal Entity

AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH

Functional Area

Qualité

Job Type

Full time

Employment Type

Regular

Shift Work

No

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