

## QA Device Manager (m/f/d) " " >

Job ID  
321144BR  
Oct 06, 2021  
Austria

### **Job Description**

#### **QA Device Manager (m/f/d), NTO Quality, Schafftenau, Austria**

74! The number of medical devices and combination product Projects in Novartis. The typical way to get biologics into the body is through an injection, so we need more and more devices, and the device can really make a difference to make our patients' life more convenient.

#### **Your key responsibilities:**

Your responsibilities include, but are not limited to:

- Responsible for implementing and maintaining the effectiveness of the quality system.
- Development, implementation and maintenance of quality processes / SOPs in medical devices based on ISO 13485, EU Medical Device Regulation and 21 CFR 820.
- Quality assurance tasks with focus on activities regarding medical devices (OOS / Deviation investigation, CAPA etc.).
- Creation / revision of QA agreements and Service Level Agreements.
- Support preparation for Medical Device Management Review.
- Self-reliant planning, organization and complete execution of audit actions.
- Implementation of risk management based on ICH Q9 and ISO 14971.
- Release activities of incoming medical device and primary packaging batches.
- Preparing and participating in inspections (Notified Body, Governmental inspections, internal and external audits).
- Conducting qualification and evaluation of suppliers.

### **Minimum Requirements**

#### **What you'll bring to the role:**

- University degree in Science (Pharmacy, Biology, Microbiology, Chemistry) or equivalent.
- A minimum of 2-3 years of professional experience in the GMP-regulated environment or in the area of medical devices.
- Experience in the area of QA / Quality.
- Ideally with a background in medical device or primary packaging and with supplier management.
- Good written and oral communications skills.
- Fluent English language skills, German skills desired.

#### **Why Novartis?**

769 million lives were touched by Novartis medicines in 2020, and while we're proud of this, we know there is

so much more we could do to help improve and extend people's lives.

We believe new insights, perspectives and ground-breaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working.

We believe our potential can thrive and grow in an unbossed culture underpinned by integrity, curiosity and flexibility. And we can reinvent what's possible, when we collaborate with courage to aggressively and ambitiously tackle the world's toughest medical challenges. Because the greatest risk in life, is the risk of never trying!

### **Imagine what you could do here at Novartis!**

In addition to a market-competitive base salary, we offer an attractive incentive program, a modern company pension scheme, childcare facilities, learning and development options as well as worldwide career opportunities 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 € 52.204,11 / year (on a full time basis). In most cases, the actual salary will be 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 work environment and diverse team's representative of the patients and communities we serve.

Our recruitment decisions are based on selecting the best person for the job, regardless of gender, religion, age, colour, race, sexual orientation, nationality or disability.

**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>

Division

Novartis Technical Operations

Business Unit

NTO QUALITY

Location

Austria

Site

Schaftenau

Company / Legal Entity

Sandoz GmbH

Functional Area

Quality

Job Type

Full Time

Employment Type

Regular

Shift Work

No

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