Our Quality Assurance group ensures every single material inside our products is manufactured, processed, tested, packaged, stored and distributed aligned with our incredibly high standards of quality and meets all regulatory requirements. Partnering across our internal manufacturing facilities, external contract manufacturers and suppliers we create an interdependent global manufacturing network dedicated to deliver a compliant, reliable supply to customers and patients on time, every time, across the globe.

Our Manufacturing & Supply Division is dedicated to being the most trusted supplier of biopharmaceuticals worldwide. Our facilities, along with our external contractors, suppliers, and partners, create a reliable global manufacturing network that's devoted to delivering a high-quality, reliable supply to customers and patients on time, every time.

For our new production facility in **Krems a.d. Donau** we are looking for an experienced

Senior Specialist Quality Assurance Systems (m/f/d)
Fixed-term for 2 years
(Full-time, as soon as possible)

The Specialist Quality Assurance Systems will provide Quality support in preparation of a USDA certification and further support the site for product transfer projects according to Austrian Drug Law (AMG), European GMP, EU 2019/6 and USDA at Krems Site, Austria.

Key attributes of the position:

- Responsibility for one's own safety and that of the immediate environment.
- Perform compliance gap assessments vs USDA requirements
- Coordinate remediation action implementation ensuring timely completion.
- Perform quality remediation actions such as creation, review and approval of relevant SOPs, qualification and validation protocols and reports, manufacturing instructions, GMP documents included but not limited to warehouse, manufacturing, QC, maintenance, engineering
- Participate and support official inspections and self-inspections
- Contribute to the implementation of quality and compliance excellence for continuous improvement and increase in efficiency throughout quality and, where necessary, support initiatives at the site and company levels.
- Work collaboratively locally and globally to foster strong relationships with management and colleagues to drive a safe and compliant culture.

Qualification and Experience:

- Minimum a bachelor's degree in (Bio)chemistry, Biology, or scientific field
- Minimum 7-8 years of experience in a Pharmaceutical GMP environment
- Knowledge of USDA requirements for US animal health vaccines is of advantage
- Good knowledge of EU GMP regulations as well as (V)ICH (Veterinary International Conference on Harmonization) guidelines
- Knowledge of PDA, ISPE (International Society for Pharmaceutical Engineering) guidances
- Good project management skills
- Fluent in German and English
- Autonomy in working through one´s own responsibilities and make decisions for necessary remediation actions.

We offer:

- Unique possibility to participate in the establishment of a state-of-the-art production site
- Diversified responsibilities in an international surrounding
- Collaboration with professional and highly motivated team members
- Participation in a respectful and positive working climate
- Attractive career opportunities as well as good training and development possibilities
- Attractive company benefits

We offer an attractive salary, outstanding social benefits and an exciting work environment with varied tasks in an international environment. The minimum annual salary for this position is EUR 59.200,- and varies according to the qualifications and experience of the successful candidate. We are looking forward to receiving your application.

We are proud to be a company that embraces the value of bringing diverse, talented, and committed people together. The fastest way to breakthrough innovation is when diverse ideas come together in an inclusive environment. We encourage our

colleagues to respectfully challenge one another's thinking and approach problems collectively. We are an equal opportunity employer, committed to fostering an inclusive and diverse workplace.