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.

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.

For our site in Krems, we are currently looking for a:

Specialist in Quality Validation (m/f/d)

2 year contract
Fulltime, asap

Main Responsibilities:

- Coordinate method transfers in cross-site teams to ensure smooth implementation.
- Create and maintain essential documentation related to method transfers, including protocols, reports, and risk assessments.
- Develop and review qualification/validation documentation to ensure compliance with regulatory standards.
- Validate computerized systems as part of equipment qualifications, with a strong emphasis on data integrity principles.
- Prepare risk assessments as part of the qualification processes to identify and mitigate potential issues.
- Investigate and evaluate deviations encountered during qualifications and propose appropriate corrective actions.
- Act as a Subject Matter Expert (SME) in troubleshooting processes and systems.
- Manage changes within the Change Control System by creating and processing change requests.
- Develop and review standard operating procedures (SOPs) and test methods to accurately describe relevant processes.
- Continuously analyze laboratory processes for efficiency improvements, gather metrics, and track trends.

Requirements:

- Bachelor's degree in a relevant field or equivalent
- Proven experience of at least 2 years in method transfer, validation, and/or quality assurance within a regulated environment.
- Strong understanding of regulatory guidelines and quality management systems.
- Excellent documentation skills and proficiency in creating technical documents.
- Experience with computerized systems and data integrity principles.
- Strong analytical skills with the ability to identify trends and propose improvements.
- Excellent communication skills to effectively collaborate with cross-functional teams.
- Ability to work independently and manage multiple priorities in a fast-paced environment.

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 48.600,- 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.