

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 Manufacturing Operations teams are the people that make our products. We work in the manufacturing plants with a "Safety First, Quality Always" mindset striving for continuous improvement. We work in the local plant connected to our global manufacturing network to ensure the highest quality of raw materials, intermediates and finished products.

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

Validation and Qualification Engineer (m/f/d)

Full-time, as soon as possible

Main Responsibilities:

- Leading assigned Qualification and Validation activities.
- Preparation of qualification plans, protocols, and reports and procedures based on internal and external rules and standards.
- Planning and execution of equipment and system qualifications as well as cleaning and process validation in cooperation with equipment/process owners , contractors, and suppliers.
- Perform cycle development, Qualification and re-qualification of sterilization processes (thermal, chemical, other physical methods).
- Participation and moderation of risk analysis of equipment, systems, and processes.
- Planning and execution of Computerized Systems Validation (CSV) in corporation with IT and Process Automation.
- Supporting improvement projects and problem solving for qualification and validation activities.
- Support for change, deviation, and CAPA management.
- Assist in training new employees in equipment qualification, risk assessments, and validation exercises.
- Responsible for being compliant with our company's safety guidelines and must be capable of recognizing unsafe situations and acting safely on the job.

Requirements:

- Bachelor, Master or Engineering degree in Biotechnology, Process Engineering, (bio)chemistry, (micro)biology, or similar disciplines.
- Must be able to track qualification/requalification activites and must be able to communicate adequately (verbally/writing) at all levels of the organization.
- Experience in a GMP production company
- Experience in equipment qualification and process validation
- Strong knowledge and hands-on experience of (bio) process technology; microbiology; aseptic processing; and equipment design.
- Practical experience in the application of risk management tools.
- Excellent communication and organizational capacity and the ability of the adequate written/oral communication at all levels of the organization.
- Experience in change management and ability to manage deviations, CAPAs, etc.
- Experience in the use of continuous improvement tools and methodologies.
- Very good knowledge of MS-Office applications
- Very good knowledge of German and English (verbal and written).

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 50.000,- 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.