

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 Commissioning, Qualification and Validation (CQV) activities including but not limited to equipment, processes, cycles, sterilization, transport, etc.
- Development and approval of CQV Plans and Reports.
- Support equipment and systems owners by providing technical knowledge
- Establish and/or participate in risk analysis and assessment to support CQV activities and change management
- Support Change Management, Deviation Management, and CAPA Management process on site and timely closure of tasks from the aforementioned
- Follow GMP, company, and local regulations regarding safety and CQV activities
- Potential to be a sub-system owner for qualification and validation topic
- Support site CQV program by conducting periodic reviews, requalifications, Sanitization/Sterilization in Place (SIP) and Performance Qualifications (PQs), Commercial off-the-shelf (COTs), in addition to undertaking Subject Matter Expert responsibilities for specific topics
- Work in an interdependent team and with stakeholders to ensure facility and equipment maintains qualified and validated status
- Initiate and support continuous improvement activities within CQV and the site

Requirements:

- Degree in (Bio)Chemistry, Process Technology, Biotechnology, Pharmaceutical Technology, Engineering or comparable work experience
- Work experience or theoretical knowledge in a Pharmaceutical Company preferably in Aseptic Processing operations.
- Hands-On-Experience or knowledge of CQV, (Bio) Process Technology, Microbiology, Aseptic Processing Equipment Design
- Experienced in or knowledge on the qualification and validation of cleanrooms, sterilization processes and aseptic process media simulation
- Experience or knowledge in risk management, change management, deviations and CAPAs management
- Energetic and enthusiastic team player with innovative mindset, strategic, analytical and problem-solving skills
- Fluency in written and spoken German and English. Very good knowledge of MS-Office applications
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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 43.548,4- and varies according to the qualifications and experience of the successful candidate. We are looking forward to receiving your application.