MSD Tiergesundheit

MSD's Animal Health (MAH) division works to improve the health of animals around the world through collaborative partnerships and a deep sense of responsibility towards our customers, consumers, animals, society, and our planet. This team of energetic, independent thinkers offers one of the industry's most innovative portfolios of products, services, and technologies that serve to prevent, treat, and control diseases across all major farm and companion animal species both domestically and internationally.

MSD Animal Health is one of the top Animal Health companies in the world, providing a broad product range, with locations in more than 50 countries and marketed products in more than 140 countries. We have a strong network of manufacturing and R&D facilities.

For our new production facility in Krems we are looking for an experienced

Validation and Qualification Engineer (m/f/d)

Full-time, as soon as possible

with several years of experience in industry. You will support the management, the quality entity and the project teams during an intensive start-up phase. The position is reporting directly to the Site Validation Lead Krems.

The primary purpose of the position is to manage and drive Qualification and Validation related activities on site ensuring continued compliance with the principles of GMP as defined in current European and Austrian statute and guidance.

Key attributes of the position:

- Leading assigned Qualification and Validation activities
- Issue of Qualification Plans, Protocols and Reports and support different Equipment and Systems owners by providing technical knowledge
- Planning and execution of the qualification of equipment and systems as well as validation of processes together with the equipment/process owner, supporting contractors and vendors
- Support to set-up a site program and undertake tasks for aseptic process validation (Media Simulation) and Cleaning Validation programs
- Perform Cycle development, Qualification and Re-Qualification of sterilization processes (thermal, chemical, other physical methods)
- Establish Risk Assessment programs for Qualifications and Validations
- Participate and moderate Risk Analysis of equipment, systems and processes
- Issue and updating of standard operating procedures for qualification and validation based on internal and external guidelines and standards
- Planning and execution of Computerized Systems Validation (CSV) in cooperation with IT and Process Automation
- Supporting and facilitating in problem solving
- Supporting improvement projects and re-validation activities
- Supporting Change Management process on site and delivering assigned tasks in a timely manner
- Supporting Deviation Management process and CAPA management process on site
- Cooperation with peers and experts at site as well as within the Network of MMD

- Management of external contractors for C&Q as well as validation activities
- Issue, execution and updating of the Project Validation Master Plans with support from senior validation team members
- To be up to date with GMP, Engineering and MSD standards and effectively applying these standards at job
- Assist training new employees in equipment qualification, risk assessments and validation exercises
- Responsible for being compliant with MSD safety guidelines and must be capable of recognizing unsafe situations and acting to be safe during job
- Tracking qualification/re-qualification activities and must be able to communicate adequately (verbally/writing) to all levels within the organisation

Qualification and Experience:

- Degree in (Bio)Chemistry, Process Technology, Biotechnology, Pharmaceutical Technology, Engineering or comparable
- Work experience or theoretical knowledge in Aseptic Processing operations in a Pharmaceutical Company
- Hands-On-Experience or knowledge on (Bio) Process Technology, Microbiology, Aseptic Processing and Equipment Design
- Experienced in or knowledge on the qualification and validation of cleanrooms, sterilization processes and aseptic process media simulation
- Experience or knowledge in CSV
- Hands on experience with application of risk management tools
- Experience in working in teams and following instructions
- Experience or knowledge in change management, deviations and CAPAs management
- Experience or knowledge in the use of continuous improvement tools and methodologies
- Energetic and enthusiastic team player with innovative mindset, strategic, analytical and problem-solving skills
- Excellent communication, interpersonal and organizational skills
- Task management skills, ability to lead and motivate individuals (incl. external contractors) to complete tasks
- Accuracy, versatility, adherence to delivery dates and love for details
- Flexibility, positive attitude, cooperativeness and friendliness
- Very good knowledge of MS-Office applications
- Fluency in written and spoken German and English

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

The minimum annual salary for this position is EUR 40.134,08 and varies according to the qualifications and experience of the successful candidate.

Your role at MSD is integral to helping the world meet new breakthroughs that affect generations to come, and we're counting on your skills and inventiveness to help make meaningful contributions to global medical advancement. At MSD, we're inventing for life.

We are looking forward to your application at **https://www.msd.at/online-bewerbung**

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