MSD Tiergesundheit

Our Animal Health division is a global leader in veterinary medicine and digital solutions dedicated to the health and well-being of animals and the people who care for them. We are a global team of professionals working together to make a positive difference in animal health and well-being and supporting a safe food supply. Through our commitment to the Science of Healthier Animals®, we offer one of our industry's most innovative portfolio of pharmaceuticals, vaccines and digital health management solutions including traceability and monitoring products that serve to prevent, treat, and control diseases across all major farm and companion animal species.

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

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Specialist Quality Assurance IT, Engineering and Digitalization (m/f/d)

Full-time, as soon as possible

The Specialist Quality Assurance IT, Engineering and Digitalization will be responsible for the quality aspects of GMP computerized systems and supporting infrastructure used in site facilities, utilities, manufacturing, packaging, labeling and laboratories to ensure compliance with company policies, procedures and regulatory expectations. This includes involvement in quality-related activities for computerized systems which are required by our internal Animal Health Quality Manual or with potential for impact on product quality, patient safety or data integrity.

The position will work closely with stakeholders and subject matter experts ("SME's") from site operations, quality operations, IT, Automation and Engineering to provide evidence of quality oversight throughout the computer system lifecycle and facilitate continuous improvement. The Associate Specialist must conduct their function and roles independently, with integrity, fairness, and objectivity to protect products and patients.

Key attributes of the position:

- Collaborating with stakeholders (e.g., System Owners, Process Owners, Data Owner and Company IT Owner) to assess and select computerized systems to support GMP business processes; to ensure technologies selected meet the high-level business needs; and ensure the initial project tailoring is appropriate for the complexity and risk to accommodate the full scope of work.
- Providing the independent quality approval of key qualification / validation documentation such as policies, procedures, acceptance criteria, plans, protocols, requirements, reports and computerized system related changes to ensure compliance to company standards and applicable regulations throughout the computerized system lifecycle (including changes / modifications / deviations / variances / compliance investigations).

- Assuring site/above site system owners have Operating Level Procedures/Plans, approved by Quality, in place and routinely followed to ensure computerized system(s) remain in a validated status (e.g., problem and incident management, change control, periodic review, investigations, backup/restore, System Use and Administrative SOPs, disaster recovery plans, business continuity plans).
- Reviewing processes and supporting documentary evidence to verify that compliance activities related to computerized systems are in place and effective.
- Supporting regulatory inspection and audit activities as needed.
- Driving resolution of regulatory non-conformance for GMP computerized systems.
- Monitoring and communicating system health, compliance and other metrics updates to key stakeholders.
- Promoting GMP awareness and a culture of continuous improvement and facilitating manufacturing process improvements, laboratory operational excellence and validation activities.
- Contribute to the development and maintenance of training programs in the principles of computerized systems validation and regulatory requirements in validation, maintenance and use of computerized systems.

Qualification and Experience:

- Master´s degree, preferably in Information Technology, Engineering, Biotechnology or equivalent
- Hands-on experience and understanding of automated systems supporting pharmaceutical manufacturing, IT infrastructure and/or laboratory operations
- At least two years of experience in delivering validated IT solutions or an application support role
- Good understanding of the current pharmaceutical industry and applicable regulations (FDA/EU/ICH), with emphasis in 21 CFR Part 11, 210, 211 and 820 and local regulatory expectations
- Working knowledge of the principles, theories, and concepts of computerized system validation / compliance
- Familiarity or practical experience in the implementation of quality systems in a pharmaceutical, laboratory or biotechnology manufacturing environment
- Limited supervision required in day-to-day activities
- Operate as part of a self-directed team in carrying out day to day functions and assigning priorities
- Hands-on experience in a regulated pharmaceutical manufacturing and/or laboratory environment (Quality or Compliance role in GMP environment desired)
- Good understanding of applicable Laboratory and / or Engineering Standards related to computerized systems development, implementation & Operations
- Business engagement skills, with ability to collaborate with both technical and non-technical roles
- Experience with supporting regulatory inspections
- Excellent oral and written communication skills including persuading others and developing cross functional relationships
- Analytical problem-solving skills applied to issue identification and resolution
- Listening, integrating diverse perspectives, adding value to the achievement of team goals
- Timely decision making
- 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
- Attractive company benefits

The minimum annual salary as per collective agreement for this position is EUR 37.756,32 and varies according to the qualifications and experience of the successful candidate.

Who we are …
We are known as Merck & Co., Inc., Kenilworth, New Jersey, USA in the United States and Canada and MSD everywhere else. For more than a century, we have been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. Today, our company continues to be at the forefront of research to deliver innovative health solutions and advance the prevention and treatment of diseases that threaten people and animals around the world.

Public

What we look for …
Imagine getting up in the morning for a job as important as helping to save and improve lives around the world. Here, you have that opportunity. You can put your empathy, creativity, digital mastery, or scientific genius to work in collaboration with a diverse group of colleagues who pursue and bring hope to countless people who are battling some of the most challenging diseases of our time. Our team is constantly evolving, so if you are among the intellectually curious, join us—and start making your impact today.

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.

Search Firm Representatives Please Read Carefully
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