

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.

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

Quality Operations Manager (f/m/d)

Mission

Lead Quality Operations.

Establish and maintain the Quality Operations unit according to Austrian Drug Law, European GMP and USDA requirements at our Animal Health Vaccine manufacturing site Krems.

Main tasks

- Responsible for occupational safety, health and environment within Quality Operations department
- Lead the Quality Operations team, Coach and Develop Employees including QP
- End responsible for the Quality Assurance related activities during manufacturing and control of drug products, from starting materials inspection, intermediates to finished goods shipping
- Provide expertise knowledge to operations to resolve shop floor issues and/or implement corrections.
- Ensure deviations and complaints are evaluated by quality operations in a timely manner, escalate when needed, and support the investigation process.
- Work with QC, Supply Chain and Operations to meet business requirement (such as release on time).
- Oversee the timely coordination and completion of the Product Quality Review (PQR/APR)
- Review and approve risk assessments, change requests, deviations, investigations, and associated CAPAs
- Review and approve GMP documents according to approval matrix (SOPs, protocols, reports...)
- Support the quality risk management process
- Ensure QOps personnel is trained in the appropriate SOPs
- Support and provide guidance in qualification and validation activities.
- Assist internal Quality Initiatives and internal audits as required. Assist as needed with Health Authorities inspections.
- Responsible for QOps budget
- Provide continuous improvement of quality processes and systems by using Merck Production System (MPS), lean six sigma.

Education and Skills

- Completed scientific/technical university studies (biotechnology, chemistry, microbiology or comparable disciplines)
- More than 10 years of professional quality experience in the pharmaceutical and/or medical technology industry in various roles
- Experienced team leader and manager,
- Experienced in moderation of problem-solving working in a cross functional team
- Very good English and German skills
- Knowledge in lean (Six Sigma or similar)

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 79.600** and varies according to the qualifications and experience of the successful candidate. We are looking forward to receiving your application.