Curriculum Vitae

Personal information

Markus Weigl

Work experience

-) 09/2025 – present AGES, Vienna, Austria
Assessor for Medicinal Product Quality

- Expert scientific and theoretical assessment of documentation for human and veterinary medicinal products with regard to pharmaceutical quality in the context of marketing authorization applications, variation procedures, renewal procedures, and registration procedures across all procedure types (national, AT = RMS, AT = CMS, centralised).
- Participation in procedures within the scope of scientific advice.
- Assessment of clinical trials of medicinal products and medical devices.
- Handling notifications of quality defects in medicinal products and medical devices.
- Preparation of procedure-guiding decisions (e.g., requests for supplementary information).
- Representation of AGES MEA in national and EU/international committees in accordance with internal organisational responsibilities.
- Training employees in new guidelines and the latest scientific findings on behalf of management (e.g., after attending a conference).
- Continuous further training within the assigned area of responsibility.
- Contribution to AGES MEA public outreach by sharing and exchanging expertise to improve cooperation with academia and industry.
- Knowledge transfer to interest groups and individuals.

-) 06/2023 – 06/2025 Takeda AG, Orth an der Donau, Austria
GMP Expert (Staff Position) – Manufacturing Support

- Responsible Data Integrity Expert for production-related systems: ensuring data integrity in accordance with GMP requirements.
- Administration of equipment, facilities, and equipment documentation as system administrator.
- Leadership and coordination of Data Integrity activities in a GMP-regulated environment; preparation of technical documents and reports.

-) 11/2019 – 06/2023 Takeda AG, Orth an der Donau, Austria
GMP Specialist – GMP Support

- Deputy team lead with a focus on system support and cross-process coordination.
- Preparation and processing of deviations, as well as implementation of CAPAs in collaboration with various departments.
- Creation and implementation of change controls through interdisciplinary cooperation.
- Improvement and implementation of quality systems to ensure continuous improvement of processes and systems.
- Support during internal and external inspections: active involvement in preparation, execution, and follow-up.
- Project planning and execution: active contribution to the planning and implementation of ongoing projects, including process optimization.
- Quality-related documentation: compilation, processing, and review of SOPs, risk assessments, and forms.

-) 04/2012 – 10/2019 MSD Animal Health GesmbH, Vienna, Austria
Senior Analyst – Quality Control

- Technical lead of a product group with responsibility for planning and compliance with GMP principles and laboratory regulations.
- Assessment of analytical data and preparation of test reports after analysis in accordance with GMP requirements.
- Technical consulting and GMP support during the implementation of analytical methods and root cause investigations for OOS results.
- Training of new employees and optimization of laboratory processes regarding efficiency and compliance.
- Management of laboratory equipment: ensuring proper maintenance, calibration, and functionality.

Education and training

07/2020 – 06/2024 FH Campus Wien, Vienna, Austria
Master of Science in Biotechnological Quality Management

07/2017 – 05/2020 FH Campus Wien, Vienna, Austria
Bachelor of Science in Bioengineering

09/2006 – 06/2011 HBLVA Rosensteingasse, Vienna, Austria
Matura and Diploma in Biochemistry, Biotechnology and Genetic Engineering

Additional information

Publications

Projects

Memberships

Other Relevant Information