

Curriculum Vitae

Personal information Georg Neuwirther

Work experience

AGES GmbH - Head of IT, Austrian Medicines and Medical Devices Agency

Start date: 2014 End date: Country: Austria

AGES GmbH - Real Estate and IT Management Start date: 2003

End date: 2014 Country: Austria

Education and training

Qualification: Certified SAFe 5 Lean Portfolio Manager

Organisation: Scaled Agile, Inc

Date: 2021

Qualification: Certified SAFe 5 Agilist

Organisation: Scaled Agile, Inc

Date: 2021

Qualification: Certificate: FHIR fundamentals

Organisation: HL7 Date: 2019

Qualification: Certificate: Cobit 5.0 foundation

Organisations: ISACA Date: 2018

Qualification: Certificate: Software Architecture Foundation Level

Organisation: iSAQB Date: 2014

Qualification: Certificate: HL7 / eHealth

Organisation: HL7

Date 2011

Qualification: Certificate: SAP Solution Architect - ERP_Integration of Business Processes

Organisation: SAP

Date: 2007

Qualification: Certificate: Certificate: Certified Process Manager

Organisation: Danube University Krems

Date: 2006

Qualification: Certificate: Registered Project Management Professional Organisation: "International Project Management Association –IPMA

Date: 2001

Education: Qualifying Examination for Real Estate Trustees

Date: 1999

Education: Degree in Computer Science at Vienna University of Technology

Organisation: Vienna University of Technology Date: 1994

Additional information

Publications

Projects

Projects and initiatives in a European context:

2023 - ongoing European Shortages Monitoring Plattform (ESMP)

• Member of the ESMP implementation working group

2019 - 2024 UNICOM (unicom-project.eu)

- Workpackage lead: Implementation of ISO-IDMP compliant application forms
- Workpackage co-lead: national implementation of ISO-IDMP
 Strategy Board Member

Implementation of the New Veterinary Regulation (NVR)

- Member NVR Coordination Group
- Member Union Product Database project group

Electronic Product Information (ePI) set-up project (ePI)

Member of the project steering group

Implementation Clinical Trials system (CTIS)

• Member EU CTR Coordination Group

Implementation of EMA SPOR

- SPOR Co-chair
- Member of the SPOR Taskforce

Implementation of the Common European Submission Plattform (CESP)

Project Member

Memberships

Ongoing

- 2017 ongoing: Member IT Directors Group 2022 onging Member European Shortages Management Plattform Working Group Member and co-charing the eAF Maintenance Group (in transition)
- Member eSubmission Expert Group
- Member Human Harmonisation
- Member eCTDv4 Working Group
- Member Austrian Standards Committee 238 / Medizinische Informatik Member ISO TC 215 /WG 6 (Parmacy and medicines business)

Past

- 2016 2024: Member Network Data Board (NDB) 2022: Member of the VMP-Regulation Coordination Group
- 2022: Member of the HMA Task force on Coordination of the Implementation of the Veterinary Regulation 2020: Member of the electronic Product Information Steering Group (ePI)

- 2017 2021: Member IT Directors Executive Committee ITDEC 2017 2021: Member EU Telematics Management Board EUTMB Member of the SPOR Taskforce
- Member of the Telematics Enterprise Architecture Board TEAB

Other Relevant Information

Current focus topics:

- Digitalisation
- Data Standardisation
- Interoperability including relevant data standards and open exchange formats Artificial Intelligence
- Business aligned IT strategies, IT Governance, Change Management in complex environments Business Analysis