



## Curriculum Vitae

### Personal information **Günter Waxenecker**

#### Work experience

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1. Employer: AGES Austrian Medicines and Medical Devices Agency
  - Start date: 012023
  - End date:
  - Position: Head of Austrian Medicines and Medical Devices Agency
  - Activities:
  - Country: Austria
2. Employer: AGES Austrian Medicines and Medical Devices Agency
  - Start date: 062007
  - End date: 122022
  - Position: Coordinator Expert Group Preclinical Assessment, Senior Expert
  - Activities:

Assessment of clinical trial applications

Assessor for marketing authorization applications and for scientific advice procedures (EMA and national)

Member of the CHMP Safety working party

EMA representative to the EMA Pandemic task force since 2013

Focus: Nonclinical assessment, Expert Biologics, CMC, Immunogenicity, Biosimilars;

- Country: Austria
3. Employer: Igeneon AG
    - Start date: 072000
    - End date: 062006
    - Position: Post Doc, Project Leader, Project and Program Manager
    - Activities:

Igeneon AG, Wien (Austria)

Project Manager of G17\_AB (anti\_Gastrin AB) Jan \_ Jul 2006:

overall Project Management,direct reporting line to CEO.

Project Leader and Program Manager of IGN311:

Overall Project Management of the clinical stage program IGN311: overall project management including the clinical study program in close contact with the cooperating production partner, principal investigators and business development; Organization of the lab group for the non\_clinical project management, working on the method development and qualification of assays for drug substance analysis, developing and performing pharmacokinetic and pharmacodynamic analysis for clinical and preclinical studies, support of the scientific mode of action and support for the process development group.

Project Leader and Program Manager of IGN301 (2001\_2004):

anti\_idiotypic antibody mimicking the Lewis Y carbohydrate antigen. Development of fermentation, purification and formulation strategies; QC and serology/pharmacokinetics and pharmacodynamics for preclinical studies and Phase I study.

Post Doc:

Biochemical vaccine characterization of anti\_idiotypic antibody MMA383 \_ influence of subcloning and glycosylation on the functionality and immunogenicity. Production, purification and rhesus monkey studies with neoglycoproteins ("IGN401"). Laboratory\_Planning, arrangement and coordination of the construction project for the actual facilities.

- Country: Austria
4. Employer: Pelias AG
    - Start date: 082006
    - End date: 052007
    - Position: Director Project Management
    - Activities:

Pelias AG was a subsidiary of Intercell AG, operatively integrated into Intercell AG as of January 2007.●

Project Manager of a Pneumococcus Vaccine Jan\_May 2007:

This preclinical stage vaccine consists of three different recombinant proteins produced by E. coli, which were profiled in different murine challenge models and was under process development by an external manufacturer. As Project Manager responsible for the coordination of internal and external activities.

Project Leader of Pseudomonas Aeruginosa Vaccine Aug 2006\_ May 2007:

Responsible for the overall lead of the project of this clinical stage program, previously profiled in an academic setting – now being transferred into an industrial setting by producing new GMP material and preparing a clinical proof of concept study. The vaccine consists of a recombinant fusion protein derived from parts of two different membrane proteins from *P. aeruginosa*. This recombinant protein is a microbial fermentation product and has already been tested in two different formulations in order to trigger either mucosal or systemic humoral immune responses.

- Country: Austria

## Education and training

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1. Subject: Faculty of Mathematics and Natural Sciences of the Rheinisch Friedrich Wilhelms University
  - Start date: 2008
  - End date: 2011
  - Qualification: Master of Drug Regulatory Affairs
  - Organisation:
  - Country: Germany
2. Subject: University of Natural Resources and Life Sciences
  - Start date: 1997
  - End date: 2000
  - Qualification: Dr. rer. nat. techn.
  - Organisation:
  - Country: Austria
3. Subject: University of Natural Resources and Life Sciences
  - Start date: 1990
  - End date: 1997
  - Qualification: Diplom\_Ingenieur (eq. Masters)
  - Organisation:
  - Country: Austria
4. Subject: University of environmental pedagogy
  - Start date: 1988
  - End date: 1989
  - Qualification: Teaching degree for agricultural schools
  - Organisation:
  - Country: Austria
5. Subject: INSEAD
  - Start date: 092002
  - End date: 092002
  - Qualification: Young Managers Program
  - Organisation:
  - Country: France

## Additional information

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### Publications

[Predicting the safety of medicines in pregnancy: A workshop report.](#)

Clements JM, Hawkes RG, Jones D, Adjei A, Chambers T, Simon L, Stemplewski H, Berry N, Price S, Pirmohamed M, Piersma AH, Waxenecker G, Barrow P, Beekhuijzen MEW, Fowkes A, Prior H, Sewell F. *Reprod Toxicol*. 2020 Apr;93:199-210. doi: 10.1016/j.reprotox.2020.02.011. Epub 2020 Feb 29. PMID: 32126282

[European Immunogenicity Platform 11th Open Scientific Symposium on immunogenicity of biopharmaceuticals.](#)

Tourdot S, Quaglia CB, Chamberlain P, De Groot AS, Dellas N, Guillemare E, Kromminga A, Lotz GP, Mingozzi F, Piccoli L, Pine S, Richards S, Waxenecker G, Kramer D. *Bioanalysis*. 2020 Aug;12(15):1043-1048. doi: 10.4155/bio-2020-0150. Epub 2020 Aug 17. PMID: 32803994

[2021 White Paper on Recent Issues in Bioanalysis: Mass Spec of Proteins, Extracellular Vesicles, CRISPR, Chiral Assays, Oligos: Nanomedicines Bioanalysis: ICH M10 Section 7.1: Non-Liquid & Rare Matrices: Regulatory Inputs \(Part 1A - Recommendations on Endogenous Compounds, Small Molecules, Complex Methods, Regulated Mass Spec of Large Molecules, Small Molecule, PoC & Part 1B - Regulatory Agencies' Inputs on Bioanalysis, Biomarkers, Immunogenicity, Gene & Cell Therapy and Vaccine\).](#)

Kaur S, Alley SC, Szapacs M, Wilson A, Ciccimaro E, Su D, Henderson N, Chen L, Garofolo F, Hengel S, Jian W, Kellie JF, Lee A, Mehl J, Palandra J, Qiu H, Savoie N, Shakleya D, Staelens L, Sugimoto H, Sumner G, Welink J, Wheller R, Xue YJ, Zeng J, Zhang J, Zhou H, Wang J, Summerfield S, Kavetska O, Dillen L, Ramanathan R, Baratta M, Dasgupta A, Edmison A, Ferrari L, Fischer S, Fraier D, Haidar S, Heermeier K, James C, Ji A, Luo L, Lima Santos GM, Post N, Rosenbaum AI, Sporning S, Surapaneni S, Vinter S, Wan K, Woolf E, Kavetska O, Cho SJ, Kossary E, Prior S, Abhari MR, Soo C, Wang YM, Bandukwala A, Cherry E, Cludts I, Ghosh S, Hopper S, Ishii-Watabe A, Kirshner S, Maher K, Maxfield K, Pedras-Vasconcelos J, Saito Y, Smith D, Solstad T, Verthelyi D, Wadhwa M, Wagner L, Waxenecker G, Yan H, Zhang L. *Bioanalysis*. 2022 May;14(9):505-580. doi: 10.4155/bio-2022-0078. Epub 2022 May 17. PMID: 35578993

[2021 White Paper on Recent Issues in Bioanalysis: TAB/NAb, Viral Vector CDx, Shedding Assays: CRISPR/Cas9 & CAR-T Immunogenicity: PCR & Vaccine Assay Performance: ADA Assay Comparability & Cut Point Appropriateness \(Part 3 - Recommendations on Gene Therapy, Cell Therapy, Vaccine Assays: Immunogenicity of Biotherapeutics and Novel Modalities: Integrated Summary of Immunogenicity Harmonization\).](#)

Loo L, Harris S, Milton M, Meena, Lembke W, Berisha F, Bertholet S, Dessy F, Dodge R, Fang X, Fiscella M, Garofolo F, Gorovits B, Gupta S, Jawa V, Ishii-Watabe A, Long B, Lu Y, Mack T, McGuire K, Nolan K, Pan L, Potthoff B, Purushothama S, Smith D, Solstad T, Sonderegger I, Taddeo F, Tangri S, Wagner L, Wu B, Xu Y, Kirshner S, Verthelyi D, Yan H, Maxfield K, Pedras-Vasconcelos J, Abhari MR, Gupta S, Wu Y, Rajadhyaksha M, Andisik M, Baltrukonis D, Cherry E, Cludts I, Gunn G, Millner AH, Jordan G, Kar S, Kubiak R, Lotz GP, Palmer R, Peng K, Poetzel J, Richards S, Savoie N, Staack RF, Stubenrauch K, Wadhwa M, Waxenecker G, Yang TY, Zhang L. *Bioanalysis*. 2022 Jun;14(11):737-793. doi: 10.4155/bio-2022-0081. Epub 2022 May 17. PMID: 35578991

Regulatory Animal Testing for the Development of Medicines (Chapter 14) in *Comparative Medicine: Disorders Linking Humans with Their Animals* p. 209-218, 2017 Jensen-Jarolim, Erika (Ed.), Springer Verlag ISBN 978-3-319-47007-8

Safety and Therapeutic Efficacy of the Lewis Y Carbohydrate Specific Humanized Antibody MB311 in Patients with Malignant Effusion. Thomas Bauernhofer, Helmut Samonigg, Peter Regitnik, Werner Weitzer, Brigitte Lileg, Günter Waxenecker, Susanne Wiederkum, Manuela Kainer, Manfred Schuster, Hans Loibner, Markus Fido, Ralf Kircheis, Andreas Nechansky *Journal of Cancer Therapy* Vol.5 No.1, January 2014

[In support of the European Union biosimilar framework.](#)

Schneider CK, Borg JJ, Ehmann F, Ekman N, Heinonen E, Ho K, Hoefnagel MH, van der Plas RM, Ruiz S, van der Stappen AJ, Thorpe R, Tiitso K, Tsiftoglou AS, Vleminckx C, Waxenecker G, Welin M, Weise M, Trouvin JH; Working Party on Similar Biological (Biosimilar) Medicinal Products (BMWP); Biologicals Working Party (BWP) of the Committee for Medicinal Products for Human Use (CHMP). Nat Biotechnol. 2012 Aug;30(8):745-8; author reply 748-9. doi: 10.1038/nbt.2322.PMID: 22871707

Phase I dose escalation study with Lewis Y Carbohydrate specific humanized Mab IGN311. Daniel Oruzio, Günter Waxenecker, Christoph Aulmann, Bruno Märkl, Theodor Wagner, Geert Mudde, Manfred Schuster, Norbert Eller, Andrea Mayer, Stefan Stranner, Gottfried Himmler, Hans Loibner, Günter Schlimok, Ralf Kircheis, Andreas Nechansky. Journal of Cancer Therapy, 2011, 2, 760-771 December 2011

Biologika, Generika & Co- Was ist was? Tschabitscher, Waxenecker, Müllner. Der Hausarzt 11/2008

[Inhibition of xenograft tumor growth and down-regulation of ErbB receptors by an antibody directed against Lewis Y antigen.](#)

Farhan H, Schuster C, Klinger M, Weisz E, Waxenecker G, Schuster M, Sexl V, Mudde GC, Freissmuth M, Kircheis R. J Pharmacol Exp Ther. 2006 Dec;319(3):1459-66. doi: 10.1124/jpet.106.107318. Epub 2006 Sep 8.PMID: 16963623

[Heterogeneous alterations in human alloimmunity associated with immunization.](#)

Roddy M, Clemente M, Poggio ED, Bukowski R, Thakkar S, Waxenecker G, Loibner H, Himmler G, Hricik DE, Heeger PS. Transplantation. 2005 Aug 15;80(3):297-302. doi: 10.1097/01.tp.0000168148.56669.61.PMID: 16082322 Clinical Trial.

Improved effector functions of a therapeutic monoclonal Lewis Y-specific antibody by glycoform engineering. Schuster M, Umana P, Ferrara C, Brünker P, Gerdes C, Waxenecker G, Wiederkum S, Schwager C, Loibner H, Himmler G, Mudde GC. Cancer Res. 2005 Sep 1;65(17):7934-41.

## Projects

### Memberships

- + EWG member (European Deputy Topic Leader since 2015; Rapporteur and European Topic Leader since 2016) for Revision 3 of ICH S5 (Reproductive Toxicity)
- + Rapporteur of the Revision 4 of ICH S5 Guideline (Reproductive Toxicity) since 2019
- + Participation of an NC3Rs/MHRA organized and refunded (travel+accommodation expenses) workshop 'A future vision for nonclinical protein-based biopharmaceutical development' on 9/10 June 2014.
- + Working group member of NC3Rs/MHRA Human Tissue for Safety Pharmacology Working Group (2013-2014): NC3Rs is an independent scientific organisation, tasked by UK Government. The scientific organisation works with individuals (e.g. researchers, veterinarians and animal care staff) and organisations (e.g. universities, pharmaceutical and chemical companies, funding bodies, and regulatory authorities) to drive advances in the 3Rs.
- + Participant of the ILSI/HESI Vaccines and Adjuvants Safety Project Committee; (Public Private Partnership, Project started in 2011, finished in 2012)
- + Reviewer Biologicals
- + Reviewer Regulatory Toxicology and Pharmacology

### Other Relevant Information