



## Curriculum Vitae

Personal information **Ilona G. Reischl**

### Work experience

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1. Employer: Austrian Medicines and Medical Devices Agency
  - Start date: 012019
  - End date:
  - Position: Assessor
  - Activities: Quality Assessor for biotech and Advanced Therapy Medicinal Products in clinical trials, scientific advice and marketing authorizations, assessor for non\_interventional trials and compassionate use. Contribution to discussions on the medicines framework, in particular interfaces to other legislations Nationally and in European expert groups.
  - Country: Austria
2. Employer: Austrian Medicines and Medical Devices Agency
  - Start date: 052014
  - End date: 122018
  - Position: Head Clinical Trials
  - Activities: Administrative tasks: Process management Clinical Trials for medicinal products and medical devices, GCP inspections, non\_interventional trials, compassionate use Quality Assessor for biotech and advanced therapy medicinal products (ATMPs) in clinical trials and scientific advice, assessor for non\_interventional trials and compassionate use
  - Country: Austria
3. Employer: Austrian Medicines and Medical Devices Agency
  - Start date: 122013
  - End date: 042014
  - Position: Assessor
  - Activities: Quality Assessor for biological medicinal products and Advanced Therapy Medicinal Products in clinical trials, scientific advice and marketing authorization procedures
  - Country: Austria
4. Employer: Austrian Medicines and Medical Devices Agency
  - Start date: 012011
  - End date: 112013
  - Position: Head of Clinical Trials, Preclinical and Statistical Evaluation
  - Activities: Institute for Marketing Authorisation of Medicinal Products & Lifecycle Management; Process management for Clinical Trials, Non\_interventional trials, compassionate use, National and EMA scientific advice procedures; Quality Assessor for biotech and Advanced Therapy Medicinal Products
  - Country: Austria
5. Employer: Austrian Medicines and Medical Devices Agency
  - Start date: 032006
  - End date: 122010
  - Position: Head of Division for National Affairs
  - Activities: Institute for Science & Information; Process administration for Clinical Trials; Assessor for clinical trials, National and EMA Scientific Advice procedures; Quality Assessor for biotech and Advanced Therapy Medicinal Products
  - Country: Austria
6. Employer: US FDA, CDER
  - Start date: 082002
  - End date: 022006
  - Position: Visiting Associate
  - Activities: Office of Biotechnology Products, Division of Monoclonal Antibodies. Quality assessor. Research activities on: "The Regulation and Function of Phospholipase C gamma 1 in Lymphocyte Signaling"; Immunology, Molecular biology, animal model
  - Country: United States
7. Employer: University of Vienna
  - Start date: 081991
  - End date: 061992
  - Position: Science Manager
  - Activities: Compilation of research activities within the faculty of Natural Sciences and support in their presentation to the public.
  - Country: Austria

### Education and training

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1. Subject: NIH/NIAMS
  - Start date: 101999
  - End date: 082002
  - Qualification: NIH Visiting Fellow
  - Organisation: Fogarty International Grant; Project: "Quantitative and qualitative aspects of signal transduction by the high affinity IgE receptor, Fc epsilon RI"; Immunology, Signal Transduction
  - Country: United States
2. Subject: Southampton General Hospital
  - Start date: 101997
  - End date: 091999

- Qualification: Postdoctoral Fellow
  - Organisation: Awardee of a European Community\_funded 2\_year grant, Biomedicine Program; Project title: "The Expression and Function of the High Affinity Receptor for Immunoglobulin E in Allergic Disease"
  - Country: United Kingdom
3. Subject: Sandoz Research Institute Vienna
- Start date: 091995
  - End date: 081997
  - Qualification: Postdoctoral Fellow
  - Organisation: Continuation of PhD thesis; Immunology, Allergology
  - Country: Austria
4. Subject: University of Vienna
- Start date: 091995
  - End date: 081997
  - Qualification: PhD in Immunology
  - Organisation: PhD in Natural Sciences, Specializing in Immunology, Allergology; Thesis\_title: "Expression and Regulation of Fc epsilon RI on Antigen Presenting Cells"; conducted at the (then) Sandoz Research Institute in Vienna
  - Country: Austria
5. Subject: University of Vienna
- Start date: 101985
  - End date: 071991
  - Qualification: Degree in Pharmacy
  - Organisation: Thesis on pesticide residues in drinking water; Institute for Analytical Chemistry
  - Country: Austria

## Additional information

### Publications

J. Sutch, M. Berntgen, C. Vincenzi, Ch. Bouygues, I. Gravanis, A. Emmendoerffer, E. Kapeller, T. Chesworth, P. van Leeuwen, J. Zinserling, H. Zander, I. Reischl, M. Skvarc, A. Hunter, C. Popp, S. Aarum „Multistakeholder scientific advice for medicinal products used in combination with a medical device or a companion diagnostic in the EU -summary of a Focus group discussion“ Front. Med., 10 July 2025, Sec. Regulatory Science, Volume 12 - 2025 |<https://doi.org/10.3389/fmed.2025.1593644>

M. Schuessler-Lenz, C. Herberts, I. Reischl, S. Ruiz, P. Celis, C. Beuneu, R. Kjekén, M. Timón; *Advances in Experimental Medicine and Biology*, Volume 1430, Maria Cristina Galli, Editor; "Regulatory Aspects of Gene Therapy and Cell Therapy Products: A Global Perspective (second edition), Chapter 1: Marketing Regulatory Oversight of Advanced Therapy Medicinal Products (ATMPs) in Europe: The EMA/CAT Perspective" pp 1-22; eBook ISBN 978-3-031-34567-8, Print ISBN 978-3-031-34566-1, DOI: 10.1007/978-3-031-34567-8

C. Verbaanderd, A. Trullás Jimeno, J. Engelbergs, H. Zander, I. Reischl, A. Moreno Oliver, S. Vamvakas, C. Vleminckx, C. Bouygues, T. Girard, F. Day, Z. Frias; "Biomarker-driven developments in the context of the new regulatory framework for companion diagnostics in the European Union", *Clinical Pharmacology & Therapeutics*, Volume 114, Number 2, pp 316-324, DOI: 10.1002/cpt.2928

I. Reischl, S. Strasser "Regulatory perspective on ATMPs: device combinations" *Cell & Gene Therapy Insights* 2020; 6(8), 933–940 DOI: 10.18609/cgti.2020.103

V. Börger, D. Weiss, J.D. Anderson, F.E. Borràs, B. Bussolati, D.R.F. Carter, M. Dominici, J.M. Falcón Pérez, M. Gimona, A.F. Hill, A.M. Hoffman, D. de Kleijn, B.L. Levine, R. Lim, J. Lötvall, S.A. Mitsialis, M. Monguió Tortajada, M. Muraca, R. Nieuwland, A. Nowocin, L. O'Driscoll, L.A. Ortiz, D.G. Phinney, I. Reischl, E. Rohde, R. Sanzenbacher, C. Théry, W. Seong Toh, K.W. Witwer, S. Kiang Lim, B. Giebel Short Communication: "International Society for Extracellular Vesicles and International Society for Cell and Gene Therapy statement on extracellular vesicles from mesenchymal stromal cells and other cells: considerations for potential therapeutic agents to suppress coronavirus disease\_19" *Cytotherapy* 22 (2020) 482\_485

A.T. Reiner, K.W. Witwer, B.W.M. Vav Balkom, J. De Beer, C. Brodie, R.L. Corteling, S. Gabrielsson, M. Gimona, A.G. Ibrahim, D. De Kleijn, C.P. Lai, J. Lötvall, H.A. Del Portillo, I.G. Reischl, M. Riazifar, C. Salomon, H. Tahara, W. Seong Toh, M.H.M. Wauben, V.K. Yang, Y. Yang, R. Wee Yeh Yeo, H. Yin, B. Giebel, E. Rohde, S. Kiang Lim "Concise Review: Developing Best\_Practice Models for the Therapeutic Use of Extracellular Vesicles" *STEM CELLS Translational Medicine*. doi:10.1002/sctm.17\_0055

Boráň T, Menezes\_Ferreira M, Reischl I, Celis P, Ferry N, Gänsbacher B, Krafft H, Lipucci Di Paola M, Sladowski D, Salmikangas P. "Clinical Development and Commercialization of Advanced Therapy Medicinal Products (ATMPs) in the EU: how are the product pipeline and regulatory framework evolving?" *Hum Gene Ther Clin Dev*. 2017 May 16. doi: 10.1089/humc.2016.193; PMID: 28510497

T. Lener, M. Gimona, L. Aigner, V. Börger, E. Buzas, G. Camussi, N. Chaput, D. Chatterjee, F.A. Court, H.A. del Portillo, L. O'Driscoll, S. Fais, J.M. Falcon\_Perez, U. Felderhoff\_Mueser, L. Fraile, Y.S. Gho, A. Görgens, R.C. Gupta, A. Hendrix, D.M. Hermann, A.F. Hill, F. Hochberg, P.A. Horn, D. de Kleijn, L. Kordelas, B.W. Kramer, E.M. Krämer\_Albers, S. Laner\_Plamberger, S. Laitinen, T. Leonardi, M.J. Lorenowicz, S.K. Lim, J. Lötvall, C.A. Maguire, A. Marcilla, I. Nazarenko, T. Ochiya, T. Patel, S. Pedersen, G. Pocsfalvi, S. Pluchino, P. Quesenberry, I.G. Reischl, F.J. Rivera, R. Sanzenbacher, K. Schallmoser, I. Slaper\_Cortebach, D. Strunk, T. Tonn, P. Vader, B.W.M. van Balkom, M. Wauben, S. El Andaloussi, C. Théry, E. Rohde and B. Giebel Applying extracellular vesicles based therapeutics in clinical trials \_ an ISEV position paper; *Journal of Extracellular Vesicles* 2015, 4: 30087 \_ <http://dx.doi.org/10.3402/jev.v4.30087>

P. Salmikangas, M. Schuessler\_Lenz, S. Ruiz, P. Celis, I. Reischl, M. Menezes\_Ferreira, E. Flory, M. Renner, and N. Ferry; *Marketing Regulatory Oversight of Advanced Therapy Medicinal Products (ATMPs) in Europe: The EMA/CAT Perspective*; *Adv Exp Med Biol*. 2015; 871:103\_30. doi: 10.1007/978\_3\_319\_18618\_4\_6.

P. Celis, N. Ferry, M. Hystad, M. Schuessler\_Lenz, P.A. Doevendans, E. Flory, C. Beuneu, I. Reischl and P. Salmikangas "Advanced Therapy Medicinal Products: How to Bring Cell\_Based Medicinal Products Successfully to the Market \_ Report from the CAT\_DGTI\_GSCN Workshop at the DGTI Annual Meeting 2014" *Congress Report Transfus Med Hemother* 2015; 42:194\_199, (DOI:10.1159/000382107)

J. Joly, J. Vanlauwe, D. Van Assche, I. Reischl, F. P. Luyten „Clinical Translation“, *Tissue Engineering*, Chapter 22, 2015 Elsevier Inc. [http://dx.doi.org/10.1016/B978\\_0\\_12\\_420145\\_3.00022\\_5](http://dx.doi.org/10.1016/B978_0_12_420145_3.00022_5)

I. Reischl, P. Salmikangas, M. Menezes\_Ferreira, A. Tsiftoglou, J. Kyselovic, J.J. Borg, S. Ruiz, E. Flory, J\_H. Trouvin, P. Celis, J. Ancans, M. Timon, G. Pante, D. Sladowski, M. Lipnik\_Stangelj, and C.K. Schneider "Manufacturing, characterization and control of cell\_based medicinal products: challenging paradigms toward commercial use" *Regenerative Medicine*, 2015, Vol. 10, No. 1, Pages 65\_78 (doi: 10.2217/rme.14.65)

RG Erben, B Silva\_Lima, I Reischl, G Steinhoff, G Tiedemann, W Dalemans, A Vos, RT Janssen, K Le Blanc, GJ van Osch, FP Luyten. "White Paper on How to Go Forward with Cell\_Based Advanced Therapies in Europe." *Tissue Eng*

S. Fürst\_Ladani, I. Reischl, E. Mincheva, T. Jeary, V. Jusevicius, T. Amini "EuroMeeting Report: The New Regulatory Outlook for Medical Devices and Combination Products" DIA Global Forum \_ Reach, Vol 6, issue 3, pp 32\_34

I. Reischl & M. Menezes\_Ferreira "Advanced therapy medicinal products for whom? The different facets of hospital exemption"; Regulatory Rapporteur, The International Journal for Professionals in Regulatory Affairs, April 2013, pp 11\_13

H. G Fill & I. Reischl "Stepwise Semantic Enrichment in Health-related Public Management by Using Semantic Information Models"; Semantic Technologies for Business and Information Systems Engineering: Concepts and Applications; IGI Global; Editors: S. Smolnik, F. Teuteberg, O. Thomas, Chapter 10; p 195, 2012

CK. Schneider, P. Salmikangas, B. Jilma, B. Flamion, L. Racheva, Todorova, A. Paphitou, I. Haunerova, T. Maimets, J.H. Trouvin, E. Flory, A. Tsiftoglou, B. Sarkadi, K. Gudmundsson, M. O'Donovan, G. Migliaccio, J. Ancāns, R. Mačiulaitis, J.L. Robert, A. Samuel, J.H. Ovelgönne, M. Hystad, A. Mariusz Fal, B. Silva Lima, A. Stela Moraru, P. Turčáni, R. Zorec, S. Ruiz, L. Åkerblom, G. Narayanan, A. Kent, F. Bignami, J. George Dickson, D. Niederwieser, M.A. Figuerola\_Santos, I.G. Reischl, C. Beuneu, R. Georgiev, M. Vassiliou, A. Pychova, M. Clausen, T. Methuen, S. Lucas, M. Schüssler\_Lenz, V. Kokkas, Z. Buzás, N. MacAleenan, MC Galli, A. Linē, J. Gulbinovic, G. Berchem, M. Fraczek, M. Menezes\_Ferreira, N. Vilceanu, M. Hrubiško, P. Marinko, M. Timón, W. Cheng, GA Crosbie, N. Meade, M. Lipucci di Paola, T. VandenDriessche, P. Ljungman, L. D'Apote, O. Oliver\_Diaz, I. Büttel & P. Celis for The Committee for Advanced Therapies (CAT) "Challenges with advanced therapy medicinal products and how to meet them" Nat.Rev. Drug.Disc 9, 195\_201 (March 2010)

H.G. Fill, & I. Reischl (2009) „An Approach for Managing Clinical Trial Applications using Semantic Information Models“; 3rd International Workshop on Process-oriented information systems in healthcare (ProHealth '09).

K. DeBell, L. Graham, I. Reischl, C. Serrano, E. Bonvini, B. Rellahan "Intramolecular Regulation of Phospholipase C $\gamma$ 1 by Its C-Terminl Src Homology 2 Domain"; Mol. Cell. Biol. 2007 27: 854\_863

D. Beach, R. Gonen, Y. Bogin, I.G. Reischl, D. Yablonski „Dual role of SLP $\gamma$ 6 in mediating TCR-induced activation of PLC $\gamma$ 1“; J. Biol.Chem. 2007; Vol. 282:5, 2937\_2946

R.L. Beavil, A.J. Beavil, I.G. Reischl "IgE structure, receptors and signaling" In Holgate ST, Church MK, Lichtenstein LM.; Allergy – 3rd Edition; Mosby Elsevier Ltd. 2006:289\_308 (Book Chapter).

C.J. Serrano, R. Rawat, M.C. Veri, K. DeBell, L. Graham, E. Bonvini, B. Rellahan, I.G. Reischl "A new tyrosine phosphorylation site in PLC $\beta$ 1: The role of tyrosine 775 in immune receptor signaling"; J. Immunol. 2005; 174: 6233-6237.

Semper A.E., Heron K., Woollard A.C.S., Kochan J.P., Friedmann P.S., Church M.K., Reischl I.G. "Surface Expression of Fc $\epsilon$ RI on Langerhans' Cells of Clinically Uninvolved Skin is associated with Disease Activity in Atopic Dermatitis and also Allergic Asthma and Rhinitis"; J.Allergy Clin.Immunol. 2003; 112 (2):411\_419

J.R. Faeder, W.S. Hlavacek, I.G. Reischl, M.L. Blinov, H. Metzger, A. Redondo, C. Wofsy, B. Goldstein "Investigation of Early Events in Fc $\epsilon$ RI Signaling using a Detailed Mathematical Model"; J. Immunol. 2003; 170:3769\_3781

H. Metzger, S. Eglite, H. Haleem\_Smith, I.G. Reischl, C. Torigoe "Quantitative Aspects of Signal Transduction by the Receptor with High Affinity for IgE"; Mol. Immunology, 2002:1207\_1211

I.G. Reischl "Tacrolimus, Picrolimus, die "Neuen" in der Therapie der Atopischen Dermatitis" (German); Der Deutsche Dermatologe, May 2002, pp. 330\_332 (Review)

I.G. Reischl "IgE und seine Rezeptoren" (German); Der Deutsche Dermatologe, February 2002, pp. 76\_80 (Review)  
H.J. Gould, A.M. Gilfillan, I.G. Reischl, R. Beavil "IgE structure, receptors and signaling"; In Holgate ST, Church MK, Lichtenstein LM.; Allergy \_ 2nd Edition. London: Gower Medical Publishing 2001:243\_264 (Book Chapter).

M.C. Veri, K.E. DeBell, M.C. Seminario, A. DiBaldassarre, I. Reischl, R. Rawat, L. Graham, C. Novello, B.L. Rellahan, S. Miscia R.L. Wange, E. Bonvini "Membrane Raft-Dependent Regulation of Phospholipase C $\beta$ 1 Activation in T Lymphocytes" Mol.Cell.Biol. 2001;21:6939\_6950

I.G. Reischl "Dendritic cells and lung antigen responses"; Clin. Exp. Allergy, 2000, 30:160\_163 (Editorial)

I.G. Reischl, S. Peiritsch, K. Brown, L. Wheat, G.R. Dubois, M. Woisetschläger, G.C. Mudde "Regulation of Fc $\epsilon$ RI expression on human monocytic cells by ligand and IL $\gamma$ 4"; Clin. Exp. Allergy 2000, 30:1033\_1040

I.G. Reischl, W.R. Coward, M.K. Church "Molecular consequences of human mast cell activation following IgE – Fc epsilon RI interaction." Biochem. Pharmacol. 1999, 58:1841\_1850 (Review)

A.E. Semper, J.A. Hartley, I.G. Reischl, S.T. Holgate. "Dendritic cells in allergy", Chapter 24, pp 435\_456 In: Dendritic Cells \_ Biology and Clinical Applications, edited by M.T. Lotze and A.W. Thomson, London: Academic Press 1999 (Review)

G. R. Dubois, I. G. Reischl, S. Peiritsch, K. Brown, L. Wheat, F. Effenberger, M. Woisetschläger, and G. C. Mudde. "Regulation of Fc epsilon RI expression on monocytic cell lines"; Int.Arch.Allergy Immunol. 1999, 118:294\_295

I.G. Reischl, A. E. Semper, G. C. Mudde, and M. K. Church. "A novel regulatory mechanism for Fc epsilon RI expression in human primary monocytes"; Int.Arch.Allergy Immunol. 1999, 118:296\_297

I.G. Reischl, T. Bjerke, K. Brown, S. Peiritsch, M. Woisetschläger, N. Corvaia, G.C. Mudde "Characteristics of Fc $\epsilon$ RI Expression on Human Monocytes and Monocytic cell lines. Establishment of an in vitro Model"; Int. Arch. Allergy Immunol. 1997, 113:266\_268

I.G. Reischl, N. Corvaia, J. Unger, M. Woisetschläger, G.C. Mudde "Characterization of Fc $\epsilon$ RI expressing human monocytic cell lines (I) The role of CD45 on signal transduction in primary monocytes and cell lines"; Int. Arch. Allergy Immunol. 1997, 113:444\_453

G.C. Mudde, I.G. Reischl, N. Corvaia, A. Hren, E.M. Pöllabauer "Antigen presentation in allergic sensitization"; Immunol. Cell Biol. 1996, 74:167\_173 (Review)

I.G. Reischl, E.M. Pöllabauer, S. Peiritsch, S. Schlager, P. Gladstone, M. Woisetschläger, G.C. Mudde "The "monocytic" cell line 1937, displays typical B cell characteristics"; Immunol. Lett. 1996, 49:127\_131

I.G. Reischl, N. Corvaia, E.M. Pöllabauer, F. Effenberger, P. Kidd, B. Wolff\_Winiski, E. Krömer, G.C. Mudde "Function and regulation of Fc $\epsilon$ RI expression on monocytes from non-atopic donors"; Clin. Exp. Allergy 1996, 26:630\_641

N. Corvaia, I.G. Reischl, E. Krömer, G.C. Mudde "Modulation of Fc $\epsilon$  receptor-mediated early events by the tyrosine phosphatase CD45 in primary human monocytes. Consequences for interleukin $\gamma$ 6 production"; Eur. J. Immunol. 1995, 25: 738\_744

## Projects

Participation in activities of the CTFG/CTCG - COMBINE project

Co-lead of the Q&A on IVDs in clinical trials, and discussion groups on combined trials (completed); [https://health.ec.europa.eu/document/download/59abcc81-fd32-4546-a340-24c8fad4e2ac\\_en?filename=mdca\\_2022-10\\_en.pdf](https://health.ec.europa.eu/document/download/59abcc81-fd32-4546-a340-24c8fad4e2ac_en?filename=mdca_2022-10_en.pdf)

#### Memberships

EMA CAT (Committee for Advanced Therapies), CAT chair (Feb. 2023)

Member of the ÖGAI (Austrian Association of Allergy and Immunology)

#### Other Relevant Information

Presentation and teaching activities Participation in regulatory/biotech meeting organizing committees

Review of European Research Proposals