

Curriculum Vitae

Personal information Karin Weissner

Work experience

1. Employer: Paul Ehrlich Institut
 - Start date: 2002
 - End date:
 - Position: Scientific assessor PKPD and Toxicology, Section Safety of Medicinal Products
 - Activities: The position includes scientific assessments in Clinical Pharmacology of Monoclonal Antibodies and Vaccines, Dose setting for First_in_human trials, Toxicological risk assessments for excipients, Research on toxicokinetic modelling of aluminium adjuvants
 - Country: Germany
2. Employer: Paul Ehrlich Institut
 - Start date: 1993
 - End date: 2001
 - Position: Scientific Assessor, Section Bacterial Vaccines
 - Activities: The position included scientific and experimental work on immunological test methods in the batch control of vaccines.
 - Country: Germany
3. Employer: Centre of Pharmacology of the University hospital of the J.W. Goethe University, Schaumainkai, Frankfurt/Main, Germany (head: Prof. Dr. D. Palm)
 - Start date: 1991
 - End date: 1993
 - Position: Post_doctoral position
 - Activities: The position included research in receptor_binding and pharmacokinetics of antihypertensives, modelling of concentration_effect relationships, involvement in teaching by giving lectures and training courses in pharmacology and physiology for medical students
 - Country: Germany

Education and training

1. Subject: Paul Ehrlich Institute
 - Start date: 2008
 - End date: 2018
 - Qualification: European registered toxicologist, ERT
 - Organisation: Postgraduate training and certificate in major fields of toxicology, coordinated by the German Toxicological Society (GT), Helmholtz Zentrum, Munich
 - Country: Germany
2. Subject: Pharmacological Institute for Natural Scientists, J.W. Goethe University, Frankfurt/Main, Germany (head: Prof. Dr. Dr. E. Mutschler)
 - Start date: 1988
 - End date: 1991
 - Qualification: Doctoral degree in Pharmacology and Toxicology
 - Organisation:
 - Country:
3. Subject: J.W. Goethe University, Frankfurt/Main
 - Start date: 1982
 - End date: 1987
 - Qualification: University degree in Pharmacy
 - Organisation:
 - Country:

Additional information

Publications

Guimaraes Koch SS, Thorpe R, Kawasaki N, Lefranc MP, Malan S, Martin ACR, Mignot G, Plückthun A, Rizzi M, Shubat S, Weissner K, Balocco R. International nonproprietary names for monoclonal antibodies: an evolving nomenclature system. *MAbs*. 2022;14(1):2075078. doi: 10.1080/19420862.2022.2075078.

Balocco R, De Sousa Guimaraes Koch S, Thorpe R, Weissner K, Malan S. New INN nomenclature for monoclonal antibodies. *Lancet*. 2022;399(10319):24. doi: 10.1016/S0140-6736(21)02732-X.

Thiele T, Weissner K, Schönborn L, Funk MB, Weber G, Greinacher A, Keller-Stanislawski B. Laboratory confirmed vaccine-induced immune thrombotic thrombocytopenia: Retrospective analysis of reported cases after vaccination with ChAdOx1 nCoV-19 in Germany. *Lancet Reg Health Eur*. 2022 Jan;12:100270. doi: 10.1016/j.lanepe.2021.100270. Epub 2021 Dec 6.

Robertson JS, Loizides U, Adisa A, Lopez de la Rica Manjavacs A, Rodilla V, Strnadova C, Weissner K, Balocco R, International Nonproprietary Names (INN) for novel vaccine substances: A matter of safety, *Vaccine* 2022; 40:21-27. <https://doi.org/10.1016/j.vaccine.2021.11.054>, epub 26 Nov 2021

Hethcy C, Hartung N, Wangorsch G, Weissner K, Huisinga W. Physiology-based toxicokinetic modelling of aluminium in rat and man. *Archives Toxicology* 2021; 95:2977-3000.

Greinacher A, Thiele T, Warkentin TE, Weissner K, Kyrle PA, Eichinger S. Thrombocytopenia after ChAdOx1 nCoV-19

Vaccination. N Engl J Med 2021; 384:2092_2101

Weisser K, Göen T, Oduro JD, Wangorsch G, Hanschmann KMO, Keller_Stanislawski B. Aluminium from adjuvanted subcutaneous allergen immunotherapeutics is mainly detected in bone. Allergy 75:215_217, 2020.

Weisser K, Göen T, Oduro JD, Wangorsch G, Hanschmann KMO, Keller_Stanislawski B. Aluminium in plasma and tissues after intramuscular injection of adjuvanted human vaccines in rats. Arch Toxicol 93:2787_2796, 2019.

Weisser K, Göen T, Oduro JD, Wangorsch G, Hanschmann KMO, Keller_Stanislawski B. Aluminium toxicokinetics after intramuscular, subcutaneous, and intravenous injection of Al citrate solution in rats.

Arch Toxicol 93:37_47, 2019. Weisser K, Stübler S, Matheis W, Huisinga W. Towards toxicokinetic modelling of aluminium exposure from adjuvants in medicinal products. Regul Toxicol Pharmacol 88:310_321, 2017.

Behrendorf_Nicol HA, Weisser K and Krämer B. "BINACLE" assay for in vitro detection of active tetanus neurotoxin in toxoids. ALTEX 32(2), 2015. (winner of the ALTEX Prize, chosen as the best article of 2015 by the ALTEX Board, ALTEX Editorial Board and ALTEX Editorial Office).

Behrendorf_Nicol HA, Bonifas U, Isbrucker R, Ottiger H, Tierney R, Hanschmann KM, Weisser K, Krämer B. Results of an international transferability study of the BINACLE (binding and cleavage) assay for in vitro detection of tetanus toxicity. Biologicals 42:199_204, 2014.

Behrendorf_Nicol HA, Bonifas U, Hanschmann KM, Krämer B, Weißer K, Binding and cleavage (BINACLE) assay for the functional in vitro detection of tetanus toxin: Applicability as alternative method for the safety testing of tetanus toxoids during vaccine production. Vaccine 31(52):6247_53, 2013.

Behrendorf_Nicol HA, Bonifas U, Kegel B, Silberbach K, Krämer B, Weißer K, In vitro determination of tetanus toxicity by an endopeptidase assay linked to a ganglioside binding step. Toxicology in Vitro 24:988_994, 2010.

Behrendorf_Nicol HA, Kegel B, Bonifas U, Silberbach K, Klimek L, Weißer K, Krämer B, Residual enzymatic activity of the tetanus toxin light chain present in tetanus toxoid batches used for vaccine production. Vaccine 26:3835_3841, 2008.

Kegel B, Behrendorf_Nicol HA, Bonifas U, Silberbach K, Klimek J, Krämer B, Weißer K, An in vitro assay for detection of tetanus neurotoxin activity: using antibodies for recognizing the proteolytically generated cleavage product. Toxicology in vitro 21:1641_1649, 2007.

Weisser K, Meyer C, Mentzer D, Petzold D und Keller_Stanislawski B, Verdachtsfälle von Impfkomplicationen nach dem Infektionsschutzgesetz und Verdachtsfälle von Nebenwirkungen (von Impfstoffen) nach dem Arzneimittelgesetz vom 1.1.2004 bis zum 31.12.2005. Bundesgesundheitsbl_Gesundheitsforsch_Gesundheitsschutz 50: 1404_1417, 2007.

Weisser K und Keller_Stanislawski B, Bleibende Schäden sind eine absolute Rarität _Nebenwirkungen von Impfungen und Impfkomplicationen. Pädiatrie_hautnah, S2 (Sonderheft ‚Impf_Innovationen‘):S46_S48, 2006.

Weisser K und Keller_Stanislawski B, Meldung und Bewertung von Impfkomplicationen in Deutschland. pädiat. prax. 69:201_215, 2006.

Weisser K, Bauer K, Volkert P und Keller_Stanislawski B, Thiomersal und Impfungen. Bundesgesundheitsbl_Gesundheitsforsch_Gesundheitsschutz 47:1165_1174, 2004.

Kegel B, Bonifas U, Silberbach K, Krämer B, Weißer K, In vitro determination of specific toxicity in tetanus vaccines. Dev Biol 111:27_32, 2002.

Ebert E, Abu Karim A, Kayser T, Wenig R, Weißer K, Wirz M, Pisani G, Schäffner G und Cußler K, Optimierung und Etablierung von serologischen Methoden für die Wirksamkeitsprüfung von Immunglobulinen gegen Clostridium tetani_Toxoid. ALTEX 15(Suppl.):30_32, 1998.

K. Weißer und U. Hechler, Animal Welfare Aspects in the Quality Control of Immunobiologicals _ A Critical Evaluation of the Animal Tests in Pharmacopoeial Monographs. FRAME (Ed.), Nottingham, 1997. ISBN: 0 9501700 4 6.

de Mey C, Schroeter V, Butzer R, Jahn P, Weisser K, Wetterich U, Terhaag B, Mutschler E, Spahn_Langguth H, Palm D, and Belz GG, Dose_effect and kinetic_dynamic relationships of the β _adrenoceptor blocking properties of various doses of talinolol in healthy humans. J Cardiovasc Pharmacol 26:879_888, 1995.

Neubeck M, Fliser D, Pritsch M, Weisser K, Fliser M, Nussberger J, Ritz E, and Mutschler E, Pharmacokinetics and pharmacodynamics of lisinopril in advanced renal failure. Consequence of dose adjustment. Eur J Clin Pharmacol 46:537_543, 1994.

Witte K, Weisser K, Neubeck M, Mutschler E, Lehmann K, Hopf R, and Lemmer B, Cardiovascular effects, pharmacokinetics, and converting enzyme inhibition of enalapril after morning versus evening administration. Clin Pharmacol Ther 54:177_186, 1993.

Weisser K and Schloos J, Measurements of serum ACE activity in vitro after administration of enalapril in man cannot reflect inhibition of the enzyme in vivo. Meth Find Exp Clin Pharmacol 15:413_418, 1993.

Weisser K, Schloos J, Jakob S, Mühlberg W, Platt D and Mutschler E, The influence of hydrochlorothiazide on the pharmacokinetics of enalapril in elderly patients. Eur J Clin Pharmacol 43:173_177, 1992.

Weisser K and Schloos J, The role of enzyme and substrate concentration in the evaluation of serum angiotensin converting enzyme (ACE) inhibition by enalaprilat in vitro. Biochem Pharmacol 42: 1729_1737, 1991.

Weisser K, Schloos J, Lehmann K, Düsing R, Vetter H and Mutschler E, Pharmacokinetics and converting enzyme inhibition after morning and evening administration of oral enalapril to healthy subjects. Eur J Clin Pharmacol 40: 95_99, 1991.

Projects

Development of a PBTK_model for aluminium exposure from adjuvants in medicinal products (funded by the German Federal Ministry of Health; 2015 _ 2018)

Development of an in vitro method for detecting residual tetanus toxicity in vaccines (funded by the German Federal Ministry of Education and Research, the foundations "Animalfree Research", and "Doerenkamp_Zbinden"; 2000 _ 2012)

Animal Welfare Aspects in the Quality Control of Immunobiologicals _ A Critical Evaluation of the Animal Tests in Pharmacopoeial Monographs (funded by the German Federal Ministry of education and Research; 1993_1996)

Memberships

Member of the INN (International Nonproprietary Name) Expert Group at WHO (Expert status)

Member of the CHMP Excipients Drafting Group (ExcpDG) for the revision of the EC guideline 'Excipients in the labelling and package leaflet of medicinal products for human use'

Member of the German Society for Experimental and Clinical Pharmacology and Toxicology (DGPT)

Research award for the promotion of methodological work aimed at reducing and replacing animal experimentation by the German ministry of food and agriculture (2010)

Other Relevant Information