



## Curriculum Vitae

Personal information **Jan Welink**

### Work experience

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1. Employer: Medicines Evaluation Board, Utrecht
  - Start date: 2002
  - End date:
  - Position: senior clinical assessor
  - Activities: dossier assessment with regard to pharmacokinetics
  - Country: Netherlands
2. Employer: Medicines Evaluation Board, The Hague
  - Start date: 1997
  - End date: 2002
  - Position: clinical assessor
  - Activities: dossier assessment with regard to pharmacokinetics
  - Country: Netherlands
3. Employer: Free University Hospital, Department of Oncology, Amsterdam
  - Start date: 1992
  - End date: 1997
  - Position: Research fellow
  - Activities: development and validation of bio\_analyses of cytostatica and involvement in clinical studies with regard to the pharmacokinetics of cytostatica
  - Country: Netherlands

### Education and training

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1. Subject: State University, Utrecht
  - Start date: 1984
  - End date: 1991
  - Qualification: masters degree
  - Organisation: Pharmaceutical sciences
  - Country: Netherlands
2. Subject: VWO, Hardenberg
  - Start date: 1982
  - End date: 1984
  - Qualification: student
  - Organisation: secondary science education
  - Country: Netherlands
3. Subject: HAVO, Hardenberg
  - Start date: 1980
  - End date: 1982
  - Qualification: student
  - Organisation: general higher secondary education
  - Country: Netherlands
4. Subject: MAVO, Coevorden
  - Start date: 1976
  - End date: 1980
  - Qualification: student
  - Organisation: general secondary education
  - Country: Netherlands

### Additional information

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#### Publications

G.M. Dorrestein, J. Welink and N. Haagsma, Pharmacokinetic differences for doxycycline between racing pigeons (*Columba livia*) and collared doves (*Streptopelia decaocto*) and the effect of a *Salmonella* infection, Proc. Deutsche Veterinarmedizinische Gesellschaft e.V., Vogelkrankheiten 7 (1990) 132\_143. I. Klein, J. Welink and W.J.F. van der Vijgh, Determination of Elsamitruicin (BMY\_28090) in plasma and urine by HPLC with fluorescence detection, J. Chromatogr. 622 (1993) 249\_253. J. Welink, B. Pechstein and W.J.F. van der Vijgh, Determination of the two diastereoisomers of lobaplatin (D\_19466) in plasma ultrafiltrate of cancer patients with a normal or an impaired kidney or liver function by high\_performance liquid chromatography with ultraviolet detection, J. Chromatogr. B, 675 (1996) 107\_111. G. Giaccone, S.C. Linn, J. Welink, G. Catimel, H. Stieltjes, W.J.F. van der Vijgh, C. Eeltink, J.B. Vermorken, H.M. Pinedo, A dose\_finding and pharmacokinetic study of reversal of multidrug resistance with SDZ PSC 833 in combination with doxorubicin in patients with solid tumors. Clin. Cancer Res.3 (1997) 2005\_2015. J. Welink, E. Boven, J.B. Vermorken, H.E. Gall, W.J.F. van der Vijgh, Pharmacokinetics and pharmacodynamics of lobaplatin (D\_19466) in patients with advanced solid tumors, including patients with impaired renal or liver function. Clin. Cancer Res. 5 (1999) 2349\_2358. M. Verschraagen, T.H. Zwiers, P.E. de Koning, J. Welink and W.J.F. van der Vijgh, Quantification of BNP7787 (dimesna) and its metabolite mesna in human plasma and urine by high\_performance liquid chromatography with electrochemical detection. J. Chromatogr. B. Biomed. Sci. Appl. (2001) 753 (2) 293\_302. Vogelpoel H, Welink J, Amidon GL, Junginger HE, Midha KK, Möller H, Olling M, Shah VP, Barends DM. Biowaiver monographs for immediate release solid oral dosage forms based on biopharmaceutics classification system (BCS) literature data: verapamil hydrochloride, propranolol hydrochloride, and atenolol. J Pharm Sci. 2004 Aug;93(8):1945\_56. Maliepaard M, Hekster YA, Kappelle A, van Puijenbroek EP, Elferink AJ, Welink J, Gispen\_de Wied CC, Lekkerkerker FJ. Requirements for generic anti\_epileptic medicines: a regulatory perspective.

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Desilva B, Garofolo F, Rocci M, Martinez S, Dumont J, Landry F, Dicaire C, Szekely\_Klepser G, Weiner R, Arnold M, Bansal S, Bateman K, Bauer R, Booth B, Davis S, Dudal S, Gouty D, Grundy J, Haider S, Hayes R, Jemal M, Kaur S, Kelley M, Knutsson M, Le Blaye O, Lee J, Lowes S, Ma M, Mitsuko T, Neto JT, Nicholson R, Ormsby E, Sailstad J, Stevenson L, Tang D, Welink J, Viswanathan C, Wang L, Woolf E, Yang E. Bioanalysis. 2012 Sep; 4(18): 2213-2226. Gwaza L, Gordon J, Welink J, Potthast H, Hansson H, Stahl M, Garcia\_Arieta A. Statistical approaches to indirectly compare bioequivalence between generics: a comparison of methodologies employing artemether/lumefantrine 20/120 mg tablets as prequalified by WHO. Eur. J. Clin. Pharmacol. 2012 Dec. 68(12): 1611-1618. Lauren Stevenson, Fabio Garofolo, Binodh DeSilva, Isabelle Dumont, Suzanne Martinez, Mario Rocci, Lakshmi Amaravadi, Margarete Brudny\_Kloepffel, Adrien Musuku, Brian Booth, Catherine Dicaire, Laura Wright, Laurence Mayrand\_Provencher, Mike Losauro, Dominique Gouty, Mark Arnold, Surendra Bansal, Sherri Dudal, Dawn Dufield, Jeff Duggan, Christopher Evans, Eric Fluhler, Stephanie Fraser, Boris Gorovits, Sam Haidar, Roger Hayes, Richard Houghton, Stacy Ho, Rafiqul Islam, Rand Jenkins, Noriko Katori, Surinder Kaur, Marian Kelley, Magnus Knutsson, Jean Lee, Hanlan Liu, Steve Lowes, Mark Ma, Alvydas Mikulskis, Heather Myler, Bob Nicholson, Vincenzo Pucci, Timothy Olah Eric Ormsby, Shefali Patel, Chad Ray, Gary Schultz, Judy Shih, Ronald Shoup, Craig Simon, An Song, João Tavares Neto, Valerie Theobald, Theingi Thway, Jason Wakelin\_Smith, Jian Wang Laixin Wang, Jan Welink, Emma Whale, Eric Woolf, Raymond Xu. 2013 White Paper on Recent Issues in Bioanalysis: "Hybrid" \_ The Best of LBA & LCMS. Bioanalysis. 2013 Dec; 5(23) 2903-2918. Gwaza L, Gordon J, Welink J, Potthast H, Leufkens H, Stahl M, Garcia\_Arieta A. Adjusted indirect treatment comparison of the bioavailability of WHO\_prequalified first\_line generic antituberculosis medicines. Clin Pharmacol Ther. 2014 Nov;96(5):580-8. Fluhler E, Hayes R, Garofolo F, Dumont I, Blaye OL, Arnold M, Bansal S, Verhaeghe T, Wilson A, Stevenson L, Myler H, Bauer R, Bergeron A, Bustard M, Cai XY, Carbone M, Cojocar L, Desai\_Krieger D, Duggan J, Haidar S, Ho S, Ingelse B, Katori N, Lévesque A, Lowes S, Ma M, Mettke K, Michon J, Musuku A, Olah T, Patel S, Rose M, Schultz G, Smeraglia J, Spooner N, Stouffer B, Vazvaei F, Wakelin\_Smith J, Wang J, Welink J, Whale E, Woolf E, Xue L, Yang TY. 2014 White Paper on recent issues in bioanalysis: a full immersion in bioanalysis (Part 1 \_ small molecules by LCMS). Bioanalysis. 2014 Nov;6(22):3039-49. Dufield D, Neubert H, Garofolo F, Kirkovsky L, Stevenson L, Dumont I, Kaur S, Xu K, Alley SC, Szapacs M, Arnold M, Bansal S, Haidar S, Welink J, Le Blaye O, Wakelin\_Smith J, Whale E, Ishii\_Watabe A, Bustard M, Katori N, Amaravadi L, Aubry AF, Beaver C, Bergeron A, Cai XY, Cojocar L, DeSilva B, Duggan J, Fluhler E, Gorovits B, Gupta S, Hayes R, Ho S, Ingelse B, King L, Lévesque A, Lowes S, Ma M, Musuku A, Myler H, Olah T, Patel S, Rose M, Schultz G, Smeraglia J, Swanson S, Torri A, Vazvaei F, Wilson A, Woolf E, Xue L, Yang TY. 2014 White Paper on recent issues in bioanalysis: a full immersion in bioanalysis (Part 2 \_ hybrid LBA/LCMS, ELN & regulatory agencies' input). Bioanalysis. 2014 Dec;6(23):3237-49. Jan Welink, John D Gordon, Matthias Stahl. Selection of the comparator product in the World Health Organisation Prequalification of Medicines Programme. Journal of Generic Medicines. 12/2014; 10(3-4):193-204. Gwaza L, Gordon J, Potthast H, Welink J, Leufkens H, Stahl M, Garcia\_Arieta A. Influence of point estimates and study power of bioequivalence studies on establishing bioequivalence between generics by adjusted indirect comparisons. Eur J Clin Pharmacol. 2015 Jun 24. Welink J, Fluhler E, Hughes N, Arnold M, Garofolo F, Bustard M, Coppola L, Dhodda R, Evans C, Gleason C, Haidar S, Hayes R, Heining K, Katori N, Le Blaye OL, Li W, Liu G, Lima Santos GM, Meng M, Nicholson B, Savoie N, Skelly M, Sojo L, Tampal N, de Merbel Nv, Verhaeghe T, Vinter S, Wickremesinhe E, Whale E, Wilson A, Witte B, Woolf E. 2015 White Paper on recent issues in bioanalysis: focus on new technologies and biomarkers (Part 1 \_ small molecules by LCMS). Bioanalysis. 2015 Nov;7(22):2913-25. 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Song A, Lee A, Garofolo F, Kaur S, Duggan J, Evans C, Palandra J, Donato LD, Xu K, Bauer R, Bustard M, Chen L, Cocea L, Croft S, Galliccia F, Haidar S, Hughes N, Ishii\_Watabe A, Islam R, Jones B, Kadavil J, Krantz C, Lima Santos GM, Olah T, Pedras\_Vasconcelos J, Staelens L, Saito Y, Savoie N, Scheibner K, Spitz S, Tampal N, Thomas E, Vinter S, Wakelin\_Smith J, Welink J, Zeng J, Zhou S. 2016 White Paper on recent issues in bioanalysis: focus on biomarker assay validation (BAV): (Part 2 - Hybrid LBA/LCMS and input from regulatory agencies). Bioanalysis. 2016 Dec;8(23):2457-2474. Yang E, Welink J, Cape S, Woolf E, Sydor J, James C, Goykhan D, Arnold M, Adcock N, Bauer R, Buonarati M, Ciccimaro E, Dodda R, Evans C, Garofolo F, Hughes N, Islam R, Nehls C, Wilson A, Briscoe C, Bustard M, Coppola L, Croft S, Drexler D, Ferrari L, Fraier D, Jenkins R, Kadavil J, King L, Li W, Lima Santos GM, Musuku A, Ramanathan R, Saito Y, Savoie N, Summerfield S, Sun R, Tampal N, Vinter S, Wakelin\_Smith J, Yue Q. 2016 White Paper on recent issues in bioanalysis: focus on biomarker assay validation (BAV) (Part 1 \_ small molecules, peptides and small molecule biomarkers by LCMS). Bioanalysis. 2016 Oct 7. Welink J, Yang E, Hughes N, Rago B, Woolf E, Sydor J, Coppola L, Ackermann B, Li W, Alley SC, Arnold M, Berger I, Briscoe C, Buonarati M, Bustard M, Cancilla M, Cho SJ, Duggan J, Fraier D, Garofolo F, Green R, Haidar S, Hittle L, Ishii\_Watabe A, Islam R, Jenkins R, Jones B, Kadavil J, Kassim S, Kavetska O, Blaye OL, Lee A, Liu H, Mehl J, Lima Santos GM, Musuku A, Ramanathan R, Saito Y, Savoie N, Summerfield S, Surapaneni S, Szapacs M, Tampal N, Verhaeghe T, Vinter S, Whale E. 2017 White Paper on recent issues in bioanalysis: aren't BMV guidance/guidelines 'Scientific'? (Part 1 \_ LCMS: small molecules, peptides and small molecule biomarkers). Bioanalysis. 2017 Nov;9(22):1807-1825. Neubert H, Song A, Lee A, Wei C, Duggan J, Xu K, Woolf E, Evans C, Palandra J, Laterza O, Amur S, Berger I, Bustard M, Cancilla M, Chen SC, Cho SJ, Ciccimaro E, Cludts I, Cocea L, D'Arienzo C, Danan\_Leon L, Donato LD, Garofolo F, Haidar S, Ishii\_Watabe A, Jiang H, Kadavil J, Kassim S, Kurki P, Blaye OL, Liu K, Mathews R, Lima Santos GM, Niwa M, Pedras\_Vasconcelos J, Qian M, Rago B, Saad O, Saito Y, Savoie N, Su D, Szapacs M, Tampal N, Vinter S, Wang J, Welink J, Whale E, Wilson A, Xue YJ. 2017 White Paper: rise of hybrid LBA/LCMS immunogenicity assays (Part 2: hybrid LBA/LCMS biotherapeutics, biomarkers & immunogenicity assays and regulatory agencies' inputs). Bioanalysis. 2017 Dec;9(23):1895-1912. Gupta S, Richards S, Amaravadi L, Piccoli S, Desilva B, Pillutla R, Stevenson L, Mehta D, Carrasco\_Triguero M, Neely R, Partridge M, Staack RF, Zhao X, Gorovits B, Kolaitis G, Sumner G, Stubenrauch KG, Zou L, Amur S, Beaver C, Berger I, Berisha F, Birnboeck H, Bower J, Cho SJ, Cludts I, Cocea L, Donato LD, Fischer S, Frasier S, Garofolo F, Haidar S, Haulenbeek J, Hottenstein C, Hu J, Ishii\_Watabe A, Islam R, Jani D, Kadavil J, Kamerud J, Kramer D, Kurki P, MacMannis S, McNally J, Mullan A, Papadimitriou A, Pedras\_Vasconcelos J, Ray S, Safavi A, Saito Y, Savoie N, Fjording MS, Scheibner K, Smeraglia J, Song A, Stouffer B, Tampal N, der Strate BV, Verch T, Welink J, Xu Y, Yang TY, Yengli L, Zeng J, Zhang Y, Zhang Y, Zeng S. 2017 White Paper on recent issues in bioanalysis: a global perspective on immunogenicity guidelines & biomarker assay performance (Part 3 \_ LBA: immunogenicity, biomarkers and PK assays). Bioanalysis. 2017 Dec;9(24):1967-1996.

Mei\_Ling Chen, Henning Blume, Gerald Beuerle, Barbara Davit, Mehul Mehta, Henrike Potthast, Barbara Schug, Yu Chung Tsang, Ralph\_Steven Wedemeyer, Werner Weitschies, Jan Welink. The Global Bioequivalence Harmonization Initiative: Summary report for EUFEPS international conference. European Journal of Pharmaceutical Sciences 111 (2018) 153–157. Sullivan JO, Blake K, Berntgen M, Salmonson T, Welink J. Overview of the European Medicines Agency's Development of Product\_Specific Bioequivalence Guidelines. Clin. Pharmacol. Ther. 2018 Sep;104(3):539\_545. Jan Welink, Yuanxin Xu, Eric Yang, Amanda Wilson, Neil Henderson5, Lina Luo, Stephanie Fraser, Uma Kavita, Adrien Musuku, Christopher James, Daniela Fraier, Yan Zhang, Dina Goykhman, Scott Summerfield, Eric Woolf, Tom Verhaeghe, Nicola Hughes, Alexander Behling, KirkBrown, Alex Bulychev, Michael Buonarati, Elana Cherry, Seongeun (Julia) Cho, Isabelle Cludts, Lieve Dillen, Robert Dodge, Anna Edmison, Fabio Garofolo, Rachel Green, Sam Haidar, Charles Hottenstein, Akiko Ishii\_Watabe, Hyun Gyung Jang, Allena Ji, Barry Jones, Sean Kassim, Mark Ma, Meena, Gustavo Mendes Lima Santos, Daniel A Norris, Tate Owen, Steven Piccoli, Ragu Ramanathan, Ingo Rohl, Anton I Rosenbaum, Yoshiro Saito, Timothy Sangster, Natasha Savoie, Christopher Stebbins, Jens Sydor, Nico van de Merbel, Daniela Verthelyi, Stephen Vinter, Emma Whale. 2018 White Paper on Recent Issues in Bioanalysis: 'A global bioanalytical community perspective on last decade of incurred samples reanalysis (ISR)' (Part 1 – small molecule regulated bioanalysis, small molecule biomarkers, peptides & oligonucleotide bioanalysis). Bioanalysis. 2018 Nov;10(22): 1781–1801. Hendrik Neubert, Timothy Olah, AnitaLee, Stephanie Fraser, Robert Dodge, Omar Laterza, Matthew Szapacs, Stephen C Alley, Ola M Saad, Shashi Amur, Linzhi Chen, Elana Cherry, Seongeun (Julia) Cho, Isabelle Cludts, Lorella Di Donato, Anna Edmison, Luca Ferrari, Fabio Garofolo, Sam Haidar, Shirley Hopper, Scott Hottenstein, Akiko Ishii\_Watabe, Sean Kassim, Pekka Kurki, Gustavo Mendes Lima Santos, Gilles Miscoria, Joe Palandra, Joao Pedras\_Vasconcelos, Steven Piccoli, Sarah Rogstad, Yoshiro Saito, Natasha Savoie, Timothy Sikorski, Susan Spitz, Ludovic Staelens, Daniela Verthelyi, Stephen Vinter, Meenu Wadhwa, Yow\_Ming Wang, Jan Welink, Naidong Weng, Emma Whale, Eric Woolf, JiangWu, Haoheng Yan, Hongbin Yu, Shaolian Zhou. 2018 White Paper on Recent Issues in Bioanalysis: focus on immunogenicity assays by hybrid LBA/LCMS and regulatory feedback (Part 2 – PK, PD & ADA assays by hybrid LBA/LCMS & regulatory agencies' inputs on bioanalysis, biomarkers and immunogenicity). Bioanalysis. 2018 Nov;10(23): 1897–1917. Mei\_Ling Chen, Henning Blume, Gerald Beuerle, Mehul Mehta, Henrike Potthast, Andreas Brandt, Barbara S. Schug, Murray Ducharme, Laszlo Endrenyi, Keith Gallicano, Donald Schuirmann, Jan Welink. Summary report of second EUFEPS/AAPS conference on global harmonization in bioequivalence. European Journal of Pharmaceutical Sciences 127 (2019) 24–28. Lenić I, Blake K, Garcia\_Arieta A, Potthast H, Welink J. Overview of the European Medicines Agency's Experience With Biowaivers in Centralized Applications. Clin Transl Sci. 2019 Sep;12(5):490\_496. Booth B, Stevenson L, Pillutla R, Buonarati M, Beaver C, Fraier D, Garofolo F, Haidar S, Islam R, James C, Kadavil J, Kavetska O, Li F, Satterwhite C, Savoie N, Subramaniam S, Tampal N, Thway T, Woolf E, Blaye OL, Andisik M, Briscoe C, Cape S, Dasgupta A, Fischer S, Haidar S, Hayes R, Kamerud J, Lima Santos GM, Nehls C, Soo C, Vinter S, Whale E, Xu K, Cho SJ, Edmison A, Kassim S, Rocha TC, Welink J, Amur S, Bandukwala A, Cherry E, Hopper S, Ishii\_Watabe A, Kirshner S, Maher K, Pedras\_Vasconcelos J, Saito Y, Saunders TS, Skibeli V, Verthelyi D, Wang YM, Yan H. 2019 White Paper On Recent Issues in Bioanalysis: FDA BMV Guidance, ICH M10 BMV Guideline and Regulatory Inputs (Part 2 – Recommendations on 2018 FDA BMV Guidance, 2019 ICH M10 BMV Draft Guideline and Regulatory Agencies' Input on Bioanalysis, Biomarkers and Immunogenicity). Bioanalysis (2019) 11(23), 2099–2132. Susan Spitz, Yan Zhang, Sally Fischer, Kristina McGuire, Ulrike Sommer, Lakshmi Amaravadi, Abbas Bandukwala, Steven Eck, Fabio Garofolo, Rafiqul Islam, Gregor Jordan, Lindsay King, Yoshiro Saito, Giane Sumner, Linda Terry, Alessandra Vitaliti, Yow\_Ming Wang, Christine Grimaldi, Alison Joyce, Rachel Palmer, Matthew Andisik, Marcela Araya, Mitra Azadeh, Daniel Baltrukonis, Rebecca Elliott, Sam Haidar, Seema Kumar, Andrew Mayer, Florian Neff, Nisha Palackal, Kun Peng, Mohsen Rajabi Abhari, Christina Satterwhite, Natasha Savoie, Catherine Soo, Stephen Vinter, Jan Welink, Weili Yan, Kevin Maher, David Lanham, Sylvie Bertholet, Naveen Dakappagari, Christèle Gonneau, Cherie Green, Fabian Junker, Sumit Kar, Lisa Patti\_Diaz, Shyam Sarikonda, Megan McCausland, Priscila Camillo Teixeira, Vilma Decman, Jose Estevam, Michael Hedrick, Alberto Hidalgo Robert, Gregory Hopkins, Sandra Nuti, Shabnam Tangri, Richard Wnek, Suman Dandamudi, Arindam Dasgupta, Anna Edmison, Patrick Faustino, Michael McGuinness, Gustavo Mendes Lima Santos, Tahseen Mirza, Diaa Shakleya, Susan Stojdl, Nilufer Tampal, Jinhui Zhang, Elana Cherry, Isabelle Cludts, Andrew Exley, Akiko Ishii\_Watabe, Susan Kirshner, Joao Pedras\_Vasconcelos, Meiyu Shen, Richard Siggers, Therese Solstad, Daniela Verthelyi, Haoheng Yan, Lucia Zhang. 2020 White Paper on Recent Issues in Bioanalysis: BAV Guidance, CLSI H62, Biopharmaceutics Stability, Parallelism Testing, CyTOF and Regulatory Feedback ( Part 2A \_ Recommendations on Biopharmaceutics Stability, PK LBA Regulated Bioanalysis, Biomarkers Assays, Cytometry Validation & Innovation Part 2B \_ Regulatory Agencies' Inputs on Bioanalysis, Biomarkers, Immunogenicity, Gene & Cell Therapy and Vaccine). Bioanalysis (2021)13(5), 295\_361. Sanna Gevers, Jan Welink and Cees van Nieuwkoop. Remdesivir in COVID\_19 Patients with Impaired Renal Function. JASN (2021) 32 (2), 518\_519. Blume H, Mehta M, Beuerle G, Dorantes A, Hempel G, Jiang W, Kovar A, Lee J, Potthast H, Schug B, Seidlitz A, Tampal N, Y\_C Tsang, Walstab J, Welink J. The Global Bioequivalence Harmonisation Initiative (GBHI): Report of EUFEPS/AAPS fourth conference. Eur J Pharm Sci. 167 (2021), 1\_10.

## Projects

2003\_2005: Participation in the Special Interest Group on the Biopharmaceutics Classification System of the Federation International Pharmaceutic (FIP). 2004\_2010: Partner BioSim EU Network of Excellence.

## Memberships

2005\_2011: Member of the European Medicines Agency (EMA) Pharmacokinetic Working Party (PKWP). 2011\_2013: Vice chair of the European Medicines Agency (EMA) Pharmacokinetic Working Party (PKWP). 2013\_2019: Chair of the European Medicines Agency (EMA) Pharmacokinetic Working Party (PKWP). 2012 (July) \_ present: Member of the EUFEPS Steering Committee on Bioavailability and Biopharmaceutics 2016\_2020: Group Lead ICH M9 Working Group Biopharmaceutics Classification System\_based Biowaivers. 2018\_present: Deputy Topic Leader ICH M10 Working Group Bioanalytical method validation. 2019\_2021: Expert member of the International Generic Drug Discussion Group of the ICH. 2019\_2022: Expert member of the European Medicines Agency (EMA) Pharmacokinetic Working Party (PKWP). 2022\_present: Expert member of the European Medicines Agency (EMA) OEG guideline drafting group. 2019\_present: Regulatory Chair ICH M13 Working Group Bioequivalence

## Other Relevant Information

2003\_2008: Chair Employee Board, Medicines Evaluation Board, the Netherlands. 2004\_present: advisor/assessor WHO Prequalification programme (an approval procedure of generics within the areas of HIV/AIDS, tuberculosis and malaria). In addition, WHO\_advisor on topics related to the Prequalification programme and expert representative during workshops in Africa, Asia, Middle\_East and East\_Europe.