EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Curriculum Vitae

Personal information

Susanne Brendler-Schwaab

Work experience

1. Employer: Bundesgesundheitsamt (BGA)
   - Start date: 091989
   - End date: 061990
   - Position: scientist, research project
   - Activities: evaluation of cell transformation assay
   - Country: Germany
2. Employer: Bayer AG, Beayer Healthcare AG
   - Start date: 061990
   - End date: 092004
   - Position: study director, laboratory head, project manager, contact officer crop protection
   - Activities: mutagenicity, genotoxicity, photogenotoxicity, indicator tests, short term carcinogenicity, single dose toxicity studies, repeat dose toxicity studies 4 weeks to 3 months, project manager for capacity planning of toxicological studies in healthcare and crop protection
   - Country: Germany
3. Employer: Federal Institute for Drugs and Medical Devices (BfArM)
   - Start date: 102004
   - End date: 062005
   - Position: Unit head preclinical assessment of clinical trials
   - Activities: Preclinical assessment of clinical trial submissions according to new legislation, project management
   - Country: Germany
4. Employer: Federal Institute for Drugs and Medical Devices (BfArM
   - Start date: 072005
   - End date: 092011
   - Position: Head of project management unit, licensing division 2
   - Activities: Regulatory Affairs, project management for all kinds of marketing authorisation and post_marketing authorisation submissions (national and European), therapeutic areas gastroenterology, endocrinology, oncology, immunology, blood; national scientific advice, internal toxicological peer review
   - Country: Germany
5. Employer: Federal Institute for Drugs and Medical Devices (BfArM)
   - Start date: 102011
   - End date:
   - Position: Unit Head parallelimport, parallel distribution, licensing division 1
   - Activities: Project management + assessment of parallel trade procedures (parallel import and parallel distribution); senior toxicologist and senior regulatory affairs expert
   - Country: Germany

Education and training

1. Subject: University of Bonn
   - Start date: 101979
   - End date: 071985
   - Qualification: Biologist (Diploma)
   - Organisation: GM2 gangliosidosis, biochemistry, cell biology
   - Country: Germany
2. Subject: University of Heidelberg, German Cancer Research Center
   - Start date: 081985
   - End date: 091989
   - Qualification: PhD
   - Organisation: Dissertation on the genotoxic effect of Dialkylnitrosamines in extrahepatic tissues in vitro and in vivo, Genotoxicity
   - Country: Germany

Additional information

Publications

Full paper: S. Sonderfeld, S. Brendler, K. Sandhoff, H. Galjaard and A.T. Hoogeveen (1985) Genetic complementation in somatic cell hybrids of four variants of infantile GM2 gangliosidosis. Hum. Genet. 71, 196_200. B.L. Pool, S.Y. Brendler, R.G. Klein, S. Monarca, R. Pasquini, P. Schmezer and W.J. Zeller (1988) Effects of SO2 and NOx on toxic and genotoxic properties of chemical carcinogens: II. Short term in vivo studies. Carcinogenesis 9, No. 7, 1247_1252. S.Y. Brendler, P. Schmezer, K._J. Hutter, A. Tompa and B.L. Pool (1989) Systemic genotoxic effects of N_nitrosodimethylamine. Int. J. of Hygiene and Env. Medicine 189, 66_67. S.Y. Brendler, P. Schmezer, K._J. Hutter, A. Tompa and B.L. Pool_Zobel (1989) Systemic genotoxic effects of N_nitrosodimethylamine. In: Environmental Hygiene II, Seemayer, N.H. und Hadnagy, W. (eds.), Springer Verlag, 26_29. B.L. Pool, S.Y. Brendler, U.M. Liegibel, A. Tompa and P. Schmezer (1990) Employment of adult mammalian primary cells in toxicology: In vivo and in vitro genotoxic effects of environmentally significant N_nitrosodialkylamines in cells of liver, lung and kidney. Environmental Molecular Mutagenesis 15, 24_35. S.Y. Brendler and B.L. Pool_Zobel (1990) In situ_Perfusionstechnik zur gleichzeitigen Gewinnung intakter Lungen_ und Nierenprimärzellen mit hoher Ausbeute und Vitalität. Zeitschrift der Gesellschaft für Umwelt_Mutationsforschung (GUM). B.L. Pool_Zobel, P. Schmezer, U. Liegibel and S.Y. Brendler (1990) Analyse genotoxischer Wirkungen mit in vitro/ex vivo Systemen. Schriftenreihe Schadstoffe und Umwelt, E. Schmidt Verlag. P. Kasper, K. Müller, N. Thiele, P. Hambach, S. Brendler, S. Madle and

L. Müller (1990) Primäre Rattenhepatozyten als externes Metabolisierungssystem im Zelltransformationstest. BGA_Tätigkeitsbericht 1989, MMV_Medizin Verlag München, 364_365. P. Kasper, K. Müller, S. Brendler, N. Thiele, P. Hambach, S. Madle L. Müller (1990) Primary rat hepatocytes as external activation system for the C3H10T1/2 cell transformation assay. Mutagenesis 5, No. 6, 622. S.Y. Brendler, A. Tompa, K._J. Hutter, R. Preußmann and B.L. Pool_Zobel (1992) In vivo and in vitro genotoxicty of several N_nitrosamines in extrahepatic tissues of the rat. Carcinogenesis 13, No. 12, 2435_2441. S.Y. Brendler_Schwaab, H. Mager, H. Lehn and B. Herbold (1994) Definition of a new intralaboratory limit value for a positive UDS assay in vitro. Toxic. in Vitro 8, No. 4, 813_816. (extended abstract) S.Y. Brendler_Schwaab, P. Schmezer, U. Liegibel, S. Weber, K. Michalek, A. Tompa and B.L. Pool_Zobel (1994) Cells of different tissues for in vitro and in vivo studies in toxicology: Compilation of isolation methods. Toxic. in Vitro 8, No. 6, 1285_1302. S.Y. Brendler_Schwaab and B.A. Herbold (1997) A new method for the enrichment of single renal proximal tubular cells and their first use in the Comet assay. Mutation Res. 393, 175_178. (short communication) A. Witt, H.J. Ahr, S. Brendler_Schwaab, H. Enzmann and W. Steinke (1998) Carcinogen_induced mitochondrial DNA damage in the In Ovo model. Toxicol. In Vitro 12 (3), 329_333. E. Gocke, S. Albertini, S. Brendler_Schwaab, L. Müller, W. Suter and F.E. Würgler (1999) Genotoxicity testing of biotechnology_derived products – Report of a GUM task force. Mutation Res. 436, 137_156. B. Kersten, J. Zhang, S.Y. Brendler_Schwaab, P. Kasper and L. Müller (1999) The application of the micronucleus test in Chinese hamster V79 cells to detect drug_induced photogenotoxicity. Mutation Res. 445 (1), 55_71. B.L. Pool_Zobel, S.Y. Brendler_Schwaab, U.M. Liegibel, R.G. Klein, F. Kuchenmeister, K. Michalek and P. Schmezer (2000) In vitro and in vivo detection of chemically induced DNA_damage in primary mammalian cells derived from somatic tissue. Environment, Science and Technology: The challenge of the 21st century. Proceedings of the Second Princess Chulabhorn Science Congress, Bangkok, Thailand, November 2_6, 1992, Vol. 1, 191_205. E. Gocke, L. Müller, P.J. Guzzie, S. Brendler_Schwaab, S. Bulera, C.F. Chignell, L.M. Henderson, A. Jacobs, H. Murli, R.D. Snyder and N. Tanaka (2000) Considerations on photochemical genotoxicity: Report of the IWGTP working group, Environmen. Molec. Mutagen. 35, 173_184. A.M. Jeffrey, L. Shao, S.Y. Brendler_Schwaab, G. Schlüter and G.M. Williams (2000) Photochemical mutagenicity of phototoxic and photochemically carcinogenic fluorochinolones in comparison with the photostable moxifloxacin. Arch. Toxicol. 74, 555_559. H. Spielmann, L. Müller, D. Averbeck, M. Balls, S. Brendler_Schwaab, J.V. Castell, R. Curren, O. de Silva, N.K. Gibbs, M. Liebsch, W.W. Lovell, H.F. Merk, J.F. Nash, N.J. Neumann, W.J.W. Pape, P. Ulrich and H.W. Vohr (2000) The second ECVAM workshop on phototoxicity testing. ATLA 28, 777_814. L. Müller, S. Brendler_Schwaab, P. Kasper and B. Kersten (2001) In vitro Methoden zur Prüfung von Arzneimitteln auf phototoxische/photokanzerogene Eigenschaften. ALTEX 18, 117_121. B. Kersten, P. Kasper, S.Y. Brendler_Schwaab, L. Müller (2001) Effects of visible light absorbing chemicals in the photo_micronucleus test in Chinese hamster V79 cells. Environ. Mutagen Res. 23, 97_102. B.A. Herbold, S.Y. Brendler_Schwaab and H.J. Ahr (2001) Ciprofloxacin: in vivo genotoxicity studies. Mutation Res. 498, 193_205. B. Kersten, P.Kasper, S.Y. Brendler_Schwaab and L. Müller (2002) Use of the photo_micronucleus assay in Chinese hamster V79 cells to study photochemical genotoxicity. Mutation Res. 519, 49_66. S.Y. Brendler_Schwaab, W. Völkner, R. Fautz and B.A. Herbold (2002) Dimethylhydrazine: A reliable positive control for the short sampling time in the UDS assay in vivo. Mutation Res. 520, 57_62. E.M. Bomhard, S.Y. Brendler_Schwaab, A. Freyberger, B.A. Herbold, K.H. Leser and M. Richter (2002) O_Phenylphenol and its Sodium and Potassium Salts: A Toxicological Assessment. Critical Reviews in Toxicology 32 (6), 551_626. A. Hartmann, E. Agurell, C. Beevers, S. Brendler_Schwaab, B. Burlinson, P. Clay, A. Collins, A. Smith, G. Speit, V. Thybaud and R.R. Tice (2003) Recommendations for conducting the in vivo alkaline Comet assay. Mutagenesis Vol. 18, No. 1, 45_51. C. Ittrich, E. Deml, D. Oesterle, K. Küttler, W. Mellert, S. Brendler_Schwaab, H. Enzmann, L. Schladt, P. Bannasch, T. Haertel, O. Mönnikes, M. Schwarz, and A. Kopp_Schneider (2003) Prevalidation of a rat liver foci bioassay (RFLB) based on results from 1600 rats: a study report. Toxicologic Pathology, vol. 31, No. 1, 60_79. S.Y. Brendler_Schwaab, A. Czich, B. Epe, E. Gocke, B. Kaina, L. Müller, D. Pollet and D. Utesch (2004) Photochemical Genotoxicity: Principles and Test methods. Report of a GUM task force. Reviews in Mutation Research, Mutation Res. 566, 65_91. S.Y. Brendler_Schwaab, A. Hartmann, S. Pfuhler and G. Speit (2005) The in vivo comet assay: use and status in genotoxicity testing. Mutagenesis, Vol. 20, No. 4, 245_254. B. Burlinson, R. Tice, G. Speit, E. Agurell, S.Y. Brendler_Schwaab, A.R. Collins, P. Escobar, M. Honma, T. S. Kumaravel, M. Nakajima, Y.F. Sasaki, V. Thybaud, Y. Uno, M. Vasquez, A. Hartmann (2007) 4th International Workgroup on Genotoxicity Testing: Results of the in vivo Comet Assay Workgroup. Mutation Res. 627, Issue 1, 31_35. Karsten Spicher; Susanne Brendler_Schwaab; Christoph Schlösser; Maria Catarinolo; Sören Fütterer; Peter Langguth (2015) Differences in tissue distribution of iron from various clinically used intravenous iron complexes in fetal avian heart and liver Regulatory Toxicology and Pharmacology, Volume 73, Issue 1, October 2015, 65–7 Laroche C, Annys E, Bender H, Botelho D, Botham P, Brendler_Schwaab S, Clayton R, Corvaro M, Dal Negro G, Delannois F, Dent M, Desaintes C, Desprez B, Dhalluin S, Hartmann A, Hoffmann_Doerr S, Hubesch B, Irizar A, Manou I, Müller BP, Nadzialek S, Prieto P, Rasenberg M, Roggeband R, Rowan TG, Schutte K, van de Water B, Westmoreland C, Whelan M, Wilschut A, Zvonimir Z, Cronin MT. Finding synergies for the 3Rs _ Repeated Dose Toxicity testing: Report from an EPAA Partners' Forum Regul Toxicol Pharmacol. 2019 Aug 31;108. Marx U, Akabane T, Andersson T.B., Baker E, Beilmann M, Beken S, Brendler_Schwaab S, Cirit M, David R, Dehne E_M, Durieux I, Ewart L, Fitzpatrick S.C., Frey O, Fuchs F, Griffith L.G., Hamilton G.A., Hartung T, Hoeng J, Hogberg H, Hughes D.J., Ingber D.E., Iskandar A, Kanamori T, Kojima H, Kuehnl J, Leist M, Li B, Loskill P, Mendrick D.L., Neumann T, Pallocca G, Rusyn I, Smirnova L, Steger_Hartmann T, Tagle D.A., Tonevitsky A, Tsyb S, Trapecar M, van de Water B, van den Eijnden_van Raaij J, Vulto P, Watanabe K, Wolf A, Zhou X, Roth A (2020) t4 Workshop Report: Biology_inspired Microphysiological Systems to Advance Patient Benefit and Animal Welfare in Drug Development. Alternatives to Animal Experimentation (ALTEX), Feb. 28. Books: Eckstein, Niels Arzneimittel – Entwicklung und Zulassung Für Studium und Praxis Deutscher Apotheker Verlag 2013 ISBN 978_3_7692_5985_8 Brendler_Schwaab, S.: Book_chapter on parallel import, parallel distribution and standard marketing authorisation:

Projects

Representative for BfArM as regulatory partner organisation (national competent authority) in the EUROoC_project: Innovative Training Network "Interdisciplinary training network for advancing Organ on chip technology in Europe" EUROoC (2019-2022)

Memberships

GUM = Gesellschaft für Umweltmutationsforschung, Germany; EEMS = European Environmental Mutagen Society; DGRA = Deutsche Gesellschaft für Regulatory Affairs, Germany; EUROoCS = European Organ on Chip Society

Other Relevant Information

National expert reviewing national research project applications in the area "Alternative methods to animal testing" commissioned by the Federal Ministry of Research, 2016-2020. National expert on behalf of the Federal Ministry of Health in the independent expert panel for relevance assessment of trace substances in the environment, pilot project 2019-2021.

Expertise:

- Scientific expert for primary organ cells, genotoxicity, photo-genotoxicity, comet assay and other indicator test systems, environmental risk assessment, nano particles, acute -subchronic animal studies.
- Special interest areas environmental risk assessment, nano-pharmaceuticals, radiopharmaceuticals, organ-on-chip models, microphysiological systems, 3Rs perspectives.
- Senior expert in regulatory affairs.
- Contact person of the BfArM for the Federal Environment Agency (UBA), Germany.
- Since June 2017 Vice Chair of the J3RsWG, EMA (mandate expired).
- Since February 2012 German member of the Safety Working Party (SWP), EMA.
- Since October 2019 Vice Chair of the SWP.
- Since October 15, 2021 Chair of the SWP (mandate expired).
- Since April 19, 2022 Chair of the Non-clinical Working Party (NcWP) of the new Non-clinical Domain (EMA).
- Since November 2020 Chair of the EMA multidisciplinary expert group nitrosamines.
- Since October 2020 member of the ,,Regulatory Advisory Board" of EUROoCS.
- February 2020-March 2024 German member of the EC "Ad Hoc working group on pharmaceuticals in the

environment", chair of subgroup 7 "Improve the environmental risk assessment and its review for the human medicines".