europass Curriculum vitae

## PERSONAL INFORMATION

Susanne Brendler-Schwaab

## WORK EXPERIENCE

September 1989–June 1990

### scientist, research project

Bundesgesundheitsamt (BGA) (Germany)

evaluation of cell transformation assay

June 1990–September 2004

### study director, laboratory head, project manager, contact officer crop protection

Bayer AG, Beayer Healthcare AG (Germany)

genotoxicity, photogenotoxicity, indicator tests, short term carcinogenicity, toxicity studies, project manager for capacity planning of toxicological studies healthcare and crop protection

October 2004–June 2005

### Unit head preclinical assessment of clinical trials

Federal Institute for Drugs and Medical Devices (BfArM) (Germany)

Preclinical assessment of clinical trial submissions according to new legislation, project management

July 2005–September 2011

### Head of project management unit, licensing division 2

Federal Institute for Drugs and Medical Devices (BfArM (Germany)

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

October 2011–Present

### Unit Head parallelimport, parallel distribution and standard marketing authorisation, licensing division 1

Federal Institute for Drugs and Medical Devices (BfArM) (Germany)

Project management + assessment of parallel trade procedures (parallel import and parallel distribution) and standard marketing authorizations

## EDUCATION AND TRAINING

October 1979–July 1985

### Biologist (Diploma)

University of Bonn (Germany)

GM2 gangliosidosis, biochemistry, cell biology

August 1985–September 1989

### PhD

University of Heidelberg, German Cancer Research Center (Germany)

Dissertation on the genotoxic effect of Dialkylnitrosamines in extrahepatic tissues in vitro and in vivo, Genotoxicity

## ADDITIONAL INFORMATION

Expertise

Scientific expert for primary organ cells, genotoxicity, photo-genotoxicity, comet assay and other indicator test systems, environmental risk assessment, nano particles.

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 February 2012 German member of the Safety Working Party (SWP), EMA, since October 2019 vice chair of the SWP. Since June 2017 vice chair of J3RsWG, EMA.

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

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.

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

## Memberships

UKEMS = United Kingdom Environmental Mutagen Society

GUM = Gesellschaft für Umweltmutationsforschung, Germany

EEMS = European Environmental Mutagen Society

DGRA = Deutsche Gesellschaft für Regulatory Affairs, Germany

## Other Relevant Information