Ing. Helmut Schütz

Neubaugasse 36/11
1070 Vienna, Austria
T +43 1 231 17 46
M +43 699 107 924 58
E helmut.schuetz@bebac.at
helmut.schuetz@muv.ac.at
W https://bebac.at/
https://orcid.org/0000-0002-1167-7880
RID https://www.webofscience.com/wos/author/record/P-9407-2018
R[G] https://www.researchgate.net/profile/Helmut-Schuetz

Personal Details

Nationality Austrian
Languages Native German, fluent in spoken and written English. Μιλάει άθλια ελληνικά. LATINAE IAM OBLITUS EST.

Education

Vienna	Sep 1973 – May 1979	Higher Federal Education and Research Institute for the Chemical Industry Focus: Technical Chemistry
Vienna	Jun 8, 1979	Final examination passed with distinction
Vienna	Mar 23, 1983	Professional Designation ‘Engineer’ (Standesbezeichnung „Ingenieur”)
Lisbon	Mar 2023 –	Faculty of Pharmacy, Universidade de Lisboa: PhD candidate

Continuing Education

#	Location	Date	Conference / Workshop / Training	Organiser	Trainer(s)
		1980			
1	Vienna	Dec 8	Introduction to Multidimensional Gas Chromatography	Siemens AG	
		1981			
2	Vienna	Dec	Evaluation of bioavailability studies	Pharmakologische Untersuchungsgesellschaft	V Nitsche
		1982			
3	Vienna	Feb 1–5	Rocky Mountain BASIC I/9000	Hewlett-Packard	R Gruber
4	Vienna	Feb 25	Derivatization in Gas Chromatography	Kurt Bartelt GmbH	N Zash
5	Vienna	Apr 1	Analysis of illicit drugs	Kurt Bartelt GmbH	N Zash
		1984			
6	Vienna	Sep 6	Symposium on Sample Preparation and Isolation Techniques using Bonded Silica	ICT GmbH	R Kupferschmidt
		1985			
7	Vienna	May 28/29	Biogenic amines and their metabolites	Ludwig Boltzmann Institut für Klinische Neurobiologie	P Riederer
		1987			
8	Würzburg	Feb 9–11	Bioavailability/Bioequivalence, Pharmaceutical and Therapeutic Equivalence	Arbeitsgemeinschaft Pharmazeutische Verfahrenstechnik	
9	Freiburg	Apr 21–24	3rd European Congress of Biopharmaceutics and Pharmacokinetics	FIP, Albert-Ludwig-Universität	
10	Vienna	Nov 9–11	Pascal Operating System for HP9000 Series 200/300	Hewlett-Packard	M Makrandreou
11	Vienna	Nov 12/13	Programming in Pascal	Hewlett-Packard	M Makrandreou
		1988			
12	Vienna	Jan 18–20	5. Forum Analytik	Hewlett-Packard	
13	Uppsala	Oct 26/27	International Symposium on Coupled Column Separations	The Swedish Chemical Society	

#	Location	Date	Conference / Workshop / Training	Organiser	Trainer(s)
		1989			
14	Vienna	Jan 23–26	6. Forum Analytik	Hewlett-Packard	
15	Graz	Oct 26–28	VIII. Scientific Meeting	Österreichische Phamazeutische Gesellschaft	
		1990			
16	London	Feb 15/16	Background – Design – Analysis & Interpretation of Bioavailabilty/Bioequivalence Studies	The Royal Society of Medicine	A Pidgen
17	Geneva	Apr 17–19	4th European Congress of Biopharmaceutics and Pharmacokinetics	FIP	
18	Amsterdam	May 15–17	Bioavailability of Drugs & Pharmacokinetics	The Center for Professional Advancement	
19	Graz	Nov 5/6	Modern Methods for Drug Monitoring and their Significance for Clincal Practice	Österreichische Pharmazeutische Gesellschaft	W Lindner
20	Arlington	Dec 3–5	Analytical Methods Validation: Bioavailability, Bioequivalence and Pharmacokinetic Studies Conference	AAPS, FDA, FIP, HPB, AOAC	
		1991			
21	Vienna	Jan 21–24	8. Forum Analytik	Hewlett-Packard	
22	Palo Alto	Oct 21–23	Pharmacokinetic Modeling Workshop	Statistical Consultants Inc	C Metzler, D Weiner
23	Palo Alto	Oct 24/25	Workshop on Bioavailability / Bioequivalence	Statistical Consultants Inc	C Metzler, D Weiner
		1992			
24	Vienna	Jan 20–23	9. Forum Analytik	Hewlett-Packard	
25	Linz	Apr 28–30	LIMS – Laboratory Information Management Systems	Austrian Association for Analytical Chemistry	W Landvoigt
26	Vienna	Jun 9	Solid Phase Extraction Workshop	Hewlett-Packard	V Weigang
27	Toronto	Jun 15–18	International Open Conference on dissolution, bioavailability, bioequivalence	Canadian Health Protection Branch, U.S. FDA, USP	
28	Stockholm	Sep 2–4	Oral Modified-Release Dosage Forms: Biopharmaceutical Challenges and Clinical Implications	Drug Information Association	
29	Vienna	Sep 24	Quality assurance in the chemical laboratory	Hewlett-Packard	
30	Graz	Nov 9/10	Modified Release Formulations in Clinical Practice, Pharmaceutical Technology and Registration	Österreichische Pharmazeutische Gesellschaft	W Lindner
31	Vienna	Nov 17	Millennium 2010 Chromatography Manager	Waters Millipore	W Fleschurz
32	Bingen	Nov 24/25	GLP module Good Laboratory Practice. Basic training	Pharma Training Service	A Burt, F Gloggengießer
		1993			
33	Vienna	Jan 25–27	10. Forum Analytik	Hewlett-Packard	
34	Vienna	Feb 2	Shimadzu HPLC	ICT GmbH	R Kupferschmidt
35	Neu-Ulm	Mar 10/11	Computerized Data Handling – Current Trends in Pharmaceutical and Clinical Research	LAB, FAW, AGAH, University of Ulm	
36	Vienna	Mar 17	Chromatograpy meeting	Austrian Association for Analytical Chemistry	
37	Brussels	Apr 20–22	5th European Congress of Biopharmaceutics and Pharmacokinetics	FIP	
38	Korneuburg	Jun 23–25	Advanced HPLC seminar	inChrom	C Wolf
39	Frankfurt	Nov 26	The Main Issue is Significance – Typical Pitfalls in Clinical Trials	Colloquium Pharmaceuticum	

#	Location	Date	Conference / Workshop / Training	Organiser	Trainer(s)
		1994			
40	Vienna	Jan 15	Generics in Comparison: Bioavailability, Bioequivalence	Österreichische Pharmazeutische Gesellschaft	HW Schramm
41	Vienna	Jan/Feb	HP-UX System Administration	Rauscher IT	H Rauscher
42	Munich	Jun 14–18	Bio-International '94	FIP	
43	Vienna	Sep	Introduction to LAB / UX 2.0 LIMS	Rauscher IT	H Rauscher
		1995			
44	Vienna	Mar 23	BackOffice	Microsoft	
45	Vienna	May 24	BIOKINET 95. Kriterien der Bioäquivalenz	Biokinet	M Arrouas, A Eichinger, V Luckow, V Nitsche, H Pittner, C Wolf
46	Nuremberg	Dec 8/9	Symposium on Quality and Interchangeability of Topical Products for Local Action	EUFEPS	
		1996			
47	Vienna	May 23	BIOKINET 96. Aktuelle Entwicklungen bei der Prüfung topischer Arzneimittel mit lokaler Wirkung	Biokinet	C Valenta, V Nitsche, E Singer
48	Vienna	Nov 27	HP-Focus „ErfolgsAnalysen"	Hewlett-Packard	
		1997			
49	Munich	Jan 20/21	Clinical Research Seminar Series: Biometrics in Europe	Colloquium Pharmaceuticum	
		1999			
50	Vienna	May 20	The Path of a Drug through the Body: Bioavailability – Pharmacokinetics	Gesellschaft für Chemiewirtschaft	H Mascher
51	London	Sep 29 – Oct 1	Bio-International '99	FIP, Royal Pharmaceutical Society	
		2001			
52	London	Nov 26	Ethical considerations in clinical trials	EMEA	
		2002			
53	Athens	Apr 12–14	International Symposium On Scientific and Regulatory Aspects of Dissolution and Bioequivalence	AFEA	
		2003			
54	London	Oct 8–10	BioInternational 2003	FIP, Royal Pharmaceutical Society, AAPS, FDA	
		2004			
55	Brussels	Nov 18/19	Dissolution Testing, Bioequivalence & Bioavailability Studies	Barnett International	
		2005			
56	Amsterdam	Sep 14/15	Dissolution Testing, Bioavailability & Bioequivalence	IIR Life Sciences	
57	London	Oct 24–26	BioInternational 2005	FIP, Royal Pharmaceutical Society, AAPS	
		2006			
58	Budapest	May 22–24	5th Annual Conference on Dissolution Testing, Bioavailability & Bioequivalence	IBC Life Sciences	
59	Vienna	Jun 13	Arzneimittelzulassung in der EU – Regulatorische Rahmenbedingungen und Möglichkeiten der Mitwirkung von nationalen Experten in Beratungs- und Zulassungsverfahren	Viennese Section of the International Biometric Society (IBS)	T Lang
60	Budapest	Oct 19/20	International Regulatory Workshop on Bioequivalence and Dissolution	Hungarian Society for Experimental and Clinical Pharmacology	

#	Location	Date	Conference / Workshop / Training	Organiser	Trainer(s)
		2007			
61	Vienna	Jan 23	Blinded sample size reestimation in non-inferiority trials with binary endpoints	Viennese Section of the IBS	T Friede
62	Vienna	May 16	A general approach to two-stage tests	Viennese Section of the IBS	M Vandemeulebroecke
63	Budapest	May 23/24	Dissolution Testing, Bioavailability & Bioequivalence	informa Life Sciences	varia
64	Athens	Oct 1/2	Conference on BA/BE	EUFEPS/COST	varia
65	Lisbon	Oct 23/24	Workshop on Bioequivalence Study Design, Working to GCP and Interpreting the Guidelines	European Generic medicines Association	
66	Vienna	Nov 7	Sources of Multiplicity in Adaptive Designs	Viennese Section of the IBS	W Maurer
67	Berlin	Nov 19	Successfully planning and designing a bioequivalence (BE) study	informa Life Sciences	U Fuhr
68	Berlin	Nov 20/21	Dissolution Testing, Bioavailability & Bioequivalence	informa Life Sciences	
69	Berlin	Nov 22	Introduction to the In Vitro-In Vivo Correlation (IVIVC)	informa Life Sciences	J-M Cardot
		2008			
70	Budapest	May 14/15	Dissolution, Bioavailability and Bioequivalence	informa Life Sciences	
71	Bad Homburg	Jun 17/18	New Regulations in Bioequivalence: Revised European CHMP Note for Guidance	EUFEPS	
72	London	Jun 26/27	Dissolution Testing, Bioequivalence and Bioavailability Strategies	visiongain	
73	Zeist	Oct 1/2	Increasing predictability in gastrointestinal simulation	TNO	
74	Nuremberg	Oct 3/4	2nd World Conference on Magic Bullets (Ehrlich II)	German Association of Pharmaceutical Scientists	
75	Prague	Oct 7	Dissolution, Bioavailability and Bioequivalence	informa Life Sciences	
76	Paris	Oct 8	Symposium on Bioequivalence	European Generic medicines Association, CMD(h)	
77	London	Oct 22–24	Bio-International 2008	FIP, Royal Pharmaceutical Society, EUFEPS, AAPS	
78	Ahmedabad	Dec 1–3	Bioavailability, Bioequivalence, Pharmacokinetics & beyond	Shivrath Center of Excellence in Clinical Research	
		2009			
79	Bonn	Jan 14/15	Revised European Guidelines on Bioequivalence	EUFEPS BABP Network	
80	Budapest	May 12/13	Bioequivalence and Bioavailability	informa Life Sciences	
81	Munich	Jul 1–3	Phoenix for WinNonlin Version 6.0	Pharsight	S Davis
		2010			
82	Berlin	Mar 9	Hurdles and Pitfalls in Generic Drug Development	Parexel Germany	
83	Brussels	Apr 15/16	EMEA Draft Guideline on Validation of Bioanalytical Methods	European Bioanalytical Forum, EUFEPS	
84	Ljubljana	May 18/19	Bioequivalence and Bioavailability	informa Life Sciences	
85	London	Jun 1	3rd Symposium on Bioequivalence	European Generic medicines Association, CMD(h)	
86	Budapest	Jun 21/22	2nd International Regulatory Workshop on Bioequivalence and Dissolution	Hungarian Society for Experimental and Clinical Pharmacology	
		2011			
87	Mumbai	Jan 29/30	Biostatistics: Basic concepts & applicable principles for various designs in BE studies and data analysis	Pharma Edge Centre	

#	Location	Date	Conference / Workshop / Training	Organiser	Trainer(s)
		2011			
88	Barcelona	Feb 24/25	Revision of BE Requirements for Modified Release Products	EUFEPS BABP Network	
89	Vienna	Apr 19	On the efficiency of two-stage adaptive designs	Viennese Section of the IBS	F Bretz
90	Budapest	May 16–18	Bioavailability / Bioequivalence and Dissolution Testing	informa Life Sciences	
91	Kobe	Jun 29 – Jul 1	International Symposium on BA/BE of Oral Drug Products	FIP	
92	Brussels	Sep 20/21	2nd Annual Bioequivalence and Bioavailability Studies	Pharma IQ	
93	Berlin	Nov 8/9	Innovations in Modified Release	informa Life Sciences	
		2012			
94	Mumbai	Jan 27–29	*In vitro in vivo* Correlation (*IVIV*C), Biowaivers & Statistical Aspects of Bioequivalence in Drug Product Development	Pharma Edge Centre	
95	Moscow	May 23–25	Advanced practical training on pharmacokinetics, statistics, and analytics in Bioequivalence Studies towards Russian regulatory requirements	Chemical Diversity Research Institute	
96	Budapest	Jun 4–6	3rd International Regulatory Workshop on Bioequivalence and Dissolution	Hungarian Society for Experimental and Clinical Pharmacology	
97	Moscow	Oct 30	Drug development and registration: «Pharma-2020» Implementation Strategy	I.M. Sechenov First Moscow State Medical University	
		2013			
98	Mumbai	Jan 25–27	Advanced concepts of *IVIV*C through case studies; Biostatistical aspects of Reference-scaled & Two stage designs: A regulatory perspective	Pharma Edge Centre	
99	Bucharest	Mar 19	Bioequivalence workshop	3S Pharmacological Consultation & Research	L Endrényi
100	Budapest	May 15/16	Bioavailability/Bioequivalence, Dissolution and Biowaivers	informa Life Sciences	
101	Leuven	Jun 5/6	Bioequivalence Assessment of Oral Dosage Forms: Basic Concepts and Practical Applications	RKV Consultancy	
102	Bonn	Jun 17/18	Open Discussion Forum on the Revised European Guideline on Pharmacokinetic and Clinical Evaluation of Modified Release Dosage Forms	EUFEPS	
103	Amman	Sep 24	1st MENA Regulatory Conference on Bioequivalence, Biowaivers, Bioanalysis and Dissolution	International Pharmaceutical Research Center	
104	Athens	Sep 26–28	5th BBBB International Conference	EUFEPS, AAPS	
		2014			
105	Munich	Apr 7/8	Haemophilia Master Class: Personalized Treatment and Care	Ludwig-Maximilians-Universität München	
106	Munich	Apr 16/17	Introduction to Phoenix® for WinNonlin® Version 6.2.x & 6.3	Certara	S Davis
107	Moscow	Apr 23–25	Bioequivalence Studies in Russia: Pharmacokinetics, Statistics and Analytics	Zentiva	
108	London	Apr 30	Workshop on the impact of the revised EMA Guideline on the Pharmacokinetic and Clinical Evaluation of Modified Release Dosage Forms	European Medicines Agency, European Generic medicines Association	
109	Budapest	May 14/15	Bioavailability/Bioequivalence, Dissolution and Biowaivers	informa Life Sciences	

#	Location	Date	Conference / Workshop / Training	Organiser	Trainer(s)
		2014			
110	Budapest	May 19–21	4th International Regulatory Workshop on Bioequivalence and Dissolution	Hungarian Society for Experimental and Clinical Pharmacology	
111	Frankfurt	Jul 3	Advisory Board on Haemophilia	Baxter	
112	Vienna	Dec 2	Innovative Statistical Approaches in Drug Development	Viennese Section of the IBS	S Senn
		2015			
113	Barcelona	Jan 27	XII Congreso	Sociedad Española de Farmacia Industrial y Galénica	
114	Munich	Jan 30	Interactive Workshop PK Dosing in Haemophilia A	Baxter	
115	Amsterdam	Mar 23/24	1st International Workshop of the Global Bioequivalence Harmonisation Initiative	EUFEPS BABP Network	
116	London	Apr 30	Joint workshop on the impact of the revised EMA Guideline on the Pharmacokinetic and Clinical Evaluation of Modified Release Dosage Forms	European Medicines Agency, European Generic medicines Association	
117	Prague	May 19/20	Bioavailability, Bioequivalence, Dissolution and Biowaivers	informa Life Sciences	
118	Budapest	Nov 14	International Conference on Advances in the Area of Bioequivalence	Hungarian Society for Pharmaceutical Science, EUFEPS	
119	Kyiv	Nov 19	5th Scientific Conference “Clinical Trials of Medicines in Ukraine”	State Expert Center of the Ministry of Health of Ukraine	
		2016			
120	Lisbon	Jun 6	Scientific and Regulatory Issues in Drug Development and Bioequivalence	Sociedade Portuguesa de Ciências Farmacêuticas	J Morais, L Benet, P Languth, N Silva, P Paixão, P Macheras, C Daousani
121	Lisbon	Jun 7–10	25th Meeting	Population Approach Group Europe	
122	Rockville	Sep 15/16	2nd International Workshop of the Global Bioequivalence Harmonisation Initiative	EUFEPS BABP Network, AAPS	
123	Prague	Sep 22/23	BioBridges 2016	Institute of Pharmacology, 1st Faculty of Medicine, Charles University	
124	Budapest	Oct 10/11	2nd International Symposium on Scientific and Regulatory Advances in Complex Drugs	Hungarian Society for Pharmaceutical Science, EUFEPS	
125	Berlin	Nov 14–16	Bioequivalence, Dissolution & IVIVC	Fleming Training	M Ross
		2017			
126	Barcelona	Feb 20–21	Bioequivalence, Dissolution & IVIVC	Fleming Training	M Ross
127	Vienna	Jun 12–14	Bioequivalence, Dissolution & IVIVC	Fleming Training	M Ross
128	Prague	Sep 21	BioBridges 2017	Institute of Pharmacology, 1st Faculty of Medicine, Charles University	
129	Budapest	Oct 5/6	2nd Annual Biosimilars Forum	Viennese Section of the IBS, Hungarian Society for Clinical Biostatistics	
130	Yaroslavl	Oct 19/20	2nd International Conference «Studies of medicinal products: Simple and complex tasks»	Yaroslavl State Medical University	
131	Léon	Nov 20/21	Bioequivalence, Dissolution & IVIVC	Fleming Training	M Ross
		2018			
132	Barcelona	Mar 19–21	Bioequivalence, Dissolution & IVIVC	Fleming Training	M Ross
133	Amsterdam	Apr 12/13	3rd International Conference of the Global Bioequivalence Harmonisation Initiative	EUFEPS BABP Network	
134	Oberursel	Jun 5/6	Introduction into Basic Principles of Pharmacokinetics	Association for Applied Human Pharmacology	T Arnhold, S Glund, R Heinig, W Mück, R-S Wedemeyer
135	Amman	Sep 24/25	3rd MENA Regulatory Conference On Bioequivalence, Biowaivers, Bioanalysis and Dissolution	International Pharmaceutical Research Center	

#	Location	Date	Conference / Workshop / Training	Organiser	Trainer(s)
		2018			
136	Prague	Sep 26/27	BioBridges 2018	Institute of Pharmacology, 1st Faculty of Medicine, Charles University	
137	Budapest	Oct 25	Univariate and multivariate Bioequivalence of PK parameters	Viennese Section of the IBS, Hungarian Society for Clinical Biostatistics	T Jaki, P Pallmann
138	Budapest	Oct 26	3rd Annual Biosimilars Forum	Viennese Section of the IBS, Hungarian Society for Clinical Biostatistics	
139	Athens	Nov 7–9	Bioequivalence, Dissolution & IVIVC	Fleming Training	
		2019			
140	Vienna	May 13	Adaptive Multi-arm Multi-stage Group Sequential Design	Viennese Section of the IBS	CM Mehta
141	Vienna	Oct 8/9	Transforming Data to Insights	Viennese Section of the IBS	D Spiegelhalter
142	Budapest	Oct 17	Robust methods for assessment of average and scaled average bioequivalence	Viennese Section of the IBS, Hungarian Society for Clinical Biostatistics	R Schall, D Burger
143	Budapest	Oct 18	4th Annual Biosimilars Forum	Viennese Section of the IBS, Hungarian Society for Clinical Biostatistics	
144	Athens	Nov 4–6	Bioequivalence, Dissolution & Biowaivers	Fleming Training	M Ross
145	Bethesda	Dec 12/13	4th International Conference of the Global Bioequivalence Harmonisation Initiative	EUFEPS BABP Network, AAPS	
		2020			
146	Campinas	Feb 11–13	Network of Scientific Excellence	Sanofi	
147	Vienna	Oct 14	Some possibly useful thoughts on bioequivalence assessments in the case of sparse sampling	Viennese Section of the IBS	M Wolfsegger
		2021			
148	São Paulo	Apr 29	Seminário Internacional: Estudos em doses múltiplas para medicamentos genéricos e similares de liberação modificada – Contexto nacional e internacional	Sindusfarma	
149	Vienna	Jun 9	Platform Trials: The potentials and the caveats of adding arms	Viennese Section of the IBS	KM Lee
150	Yaroslavl	Oct 22	3rd International Conference «Studies of medicinal products: Simple and complex tasks»	Yaroslavl State Medical University	
		2022			
151	Paris	Mar 22–24	Non-compartmental Analysis, Bioequivalence & Beyond. Spring School with PKanalix™	Lixoft	
152	Vienna	Jun 22	Symmetric graphs for equally weighted tests, with application to the Hochberg procedure	Viennese Section of the IBS	F Bretz
153	Prague	Sep 22/23	BioBridges 2022	Institute of Pharmacology, 1st Faculty of Medicine, Charles University	
154	Amsterdam	Sep 28/29	5th International Conference of the Global Bioequivalence Harmonisation Initiative	EUFEPS BABP Network	
155	Oberursel	Oct 6/7	Introduction into Basic Principles of Pharmacokinetics	Association for Applied Human Pharmacology	S Glund, R Heinig, J Höchel, F Runge, R-S Wedemeyer
		2023			
156	Boston	Feb 7	Physiologically-Based Pharmacokinetic Modeling & Simulation	Certara, Novartis	
157	Silver Spring	Mar 14	Draft Guidance on Statistical Approaches to Establishing Bioequivalence	FDA CDER Small Business & Industry Assistance	

#	Location	Date	Conference / Workshop / Training	Organiser	Trainer(s)
		2023			
158	Brussels	Apr 26	2nd Bioequivalence Workshop	Medicines for Europe	
159	Silver Spring	May 2	Navigating the First ICH Generic Drug Draft Guidance "M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms"	FDA CDER Small Business & Industry Assistance	
160	Frankfurt	May 15	ICH M13 Bioequivalence Guideline Part A	EUFEPS BABP Network	
161	Athens	May 22/23	Bioavailability–Bioequivalence. From Classification to Virtualisation & Anything in Between	National and Kapodistrian University of Athens	
162	Boston	Jun 28	Unlocking Efficiency and Quality: What is New in Phoenix™ 8.4?	Certara	A Henry, L Hughes
163	Prague	Sep 21/22	BioBridges 2023	Institute of Pharmacology, 1st Faculty of Medicine, Charles University	
164	Oberursel	Oct 5/6	Introduction into Basic Principles of Pharmacokinetics	Association for Applied Human Pharmacology	S Glund, R Heinig, J Höchel, F Runge, R-S Wedemeyer
165	Frankfurt	Oct 11	Experience meets Expertise BE: New Trends and recent Discussions	SocraTec	H Blume, B Schug, P Paixão, R Michelet, A Fuglsang
166	Vienna	Oct 20	Randomisation Versus Random Sampling: Clinical Trials and the Representation Fallacy	Center for Medical Data Science, Medical University Vienna	S Senn
167	Brussels	Nov 29	Bioequivalence Working Group meeting	Medicines for Europe	A Fuglsang
168	Lisbon	Dec 11–15	Translating Nanomedicines from the Lab to the Clinic. Basic Principles for Nanomedicines R&D	Faculty of Pharmacy, University of Lisbon	
		2024			
169	Lisbon	Feb 12 – Mar 13	Advanced Pharmacy Practice Research Methods	Faculty of Pharmacy, University of Lisbon	
170	Boston	Apr 10	What is New in Phoenix™ 8.5?	Certara	A Henry
171	Rockville	Apr 16/17	6th International Workshop of the Global Bioequivalence Harmonisation Initiative	PQRI, EUFEPS, AAPS, USP	
172	Rockville	Jun 10, 13	Spring Workshop on Data Integrity in Bioequivalence Studies	SAAMnow	
173	Vienna	Jun 21	Bridging the Gap between Bayesian & Frequentist Approaches in Clinical Trials for Drug Development	Viennese Section of the IBS	
174	Lisbon	Jun 24–28	Advanced Analytical Tools – Multiple Applications for Mass Spectrometry	Faculty of Pharmacy, University of Lisbon	
175	Prague	Sep 26/27	BioBridges 2024	Institute of Pharmacology, 1st Faculty of Medicine, Charles University	
176	Oberursel	Oct 1/2	Introduction into Basic Principles of Pharmacokinetics	Association for Applied Human Pharmacology	S Glund, R Heinig, J. Höchel, F Runge, R-S Wedemeyer
177	Silver Spring	Oct 9	ICH M12 Drug-Drug Interaction Studies Final Guidance	FDA CDER Small Business & Industry Assistance	
178	Lisbon	Oct 14 – Nov 3	Molecular Biomarkers and Technologies	Faculty of Pharmacy, University of Lisbon	
179	Vienna	Nov 20	Estimands: The new bedrock of drug development?	Center for Medical Data Science, Medical University Vienna	F Bretz

#	Location	Date	Conference / Workshop / Training	Organiser	Trainer(s)
		2024			
180	Silver Spring	Nov 21	Implementing M13A Guidance: BE for IR Solid Oral Dosage Forms	FDA CDER Small Business & Industry Assistance	
		2025			
181	Amsterdam	Apr 26	3rd Bioequivalence Conference	IGBA, Medicines for Europe	
182	Vienna	May 7	News and updates from the CHMP and around the Centralized Procedure	Austrian Agency for Health and Food Safety	
183	Rockville	Jun 10–12	Spring Workshop on Statistical and Data Analysis Issues and Solutions for ANDAs and 505(b)(2) NDAs	SAAMnow	
184	Prague	Sep 25/26	BioBridges 2025	Institute of Pharmacology, 1st Faculty of Medicine, Charles University	
185	Oberursel	Oct 7/8	Introduction into basic principles of clinical pharmacokinetics	Association for Applied Human Pharmacology	S Glund, R Heinig, J. Höchel, F Runge, R-S Wedemeyer
		2026			
186	Silver Spring	Apr 22/23	Generic Drugs Forum 2026	FDA CDER Small Business & Industry Assistance	
187	Vienna	Apr 28	Standard errors in representing Fisher's views on randomisation	Center for Medical Data Science, Medical University Vienna	S Senn

Presentations

Σ	Location	Date	Conference / Workshop / Training	Title (number)
		1995		
1	Vienna	May 24	BIOKINET 95. Kriterien der Bioäquivalenz	• Die Rolle der Biometrie
		1996		
2	Vienna	May 23	BIOKINET 96. Aktuelle Entwicklungen bei der Prüfung topischer Arzneimittel mit lokaler Wirkung	• Klinische Studien mit topischen Arzneimitteln
		2004		
3	Brussels	Nov 19	Dissolution Testing, Bioequivalence & Bioavailability Studies	• Pitfalls in BA/BE-Studies
		2006		
13	Istanbul	Mar 7/8	Regulatory Update and Overview of BE and BA Testing with an Industry Perspective	• Overview of Dissolution for BA / BE • Bioavailability / Bioequivalence (9)
14	Budapest	May 24	5th Annual Conference on Dissolution Testing, Bioavailability & Bioequivalence	• Pitfalls in BA/BE-Studies
		2007		
15	Berlin	Nov 21	Dissolution Testing, Bioavailability & Bioequivalence	• Getting to grips with statistical aspects of BE studies
		2008		
16	Budapest	May 14	Dissolution, Bioavailability and Bioequivalence	• Ensuring bioanalytical compliance of your BA/BE study
17	London	Jun 27	Dissolution Testing, Bioequivalence and Bioavailability Strategies	• Considerations for planning and designing a bioequivalence (BE) study
18	Zeist	Oct 2	Increasing predictability in gastrointestinal simulation	• View of BEBAC on *in vitro* studies
20	Nuremberg	Oct 3/4	2nd World Conference on Magic Bullets (Ehrlich II)	• Bioequivalence – Still an Applied Science or already a 'Cookbook'? (2)

Σ	Location	Date	Conference / Workshop / Training	Title (number)
		2008		
21	Prague	Oct 7	Dissolution, Bioavailability and Bio-equivalence	• BA/BE design versus 'job creation scheme'
25	Ahmeda-bad	Dec 1–3	Bioavailability, Bioequivalence, Pharmacokinetics & beyond	• Analytical Development and Validation • Clinical Part of Phase I Studies • Statistical Design and Analysis • Q&A Session: Examples
32	Aesch	Dec 15	Workshop on Bioequivalence Basics	• Overview and Introduction • Analytical Development and Validation • Clinical Part of BA/BE Studies • Noncompartmental Analysis in PK, PK-based Design • Statistical Design and Analysis (3)
		2009		
39	Budapest	May 11	Bioequivalence and Bioavailability	• Best Design of BE Studies: Overview and Introduction • Analytical Development and Validation • Clinical Part of BA/BE Studies • Noncompartmental Analysis in PK, PK-based Design • Statistical Design and Analysis (3)
47	Prague	Oct 8/9	Workshop on Statistics for Bioequi-valence	• Overview and Introduction • Noncompartmental Analysis in PK, PK-based Design • Statistical Design and Analysis (2) • Outliers in cross-over BE Studies • Replicate Designs • Sequential Designs • Sample Size Estimation
		2010		
63	Ljubljana	Feb 4	Workshop on bioequivalence	• History of BE • Study Types • Simulations • Bioanalytics • Common Problems and Solutions • GCP Issues • Ethical Issues • Study Planning • Special Designs • Pilot Studies • Pitfalls in NCA • Sample Sizes • Biostatistics for BE (2)
64	Berlin	Mar 9	Hurdles and Pitfalls in Generic Drug Development	• Design and Interpretation of BE Studies – Current and Future Issues
69	Holzkir-chen	Apr 21	Bioequivalence workshop	• Noncompartmental Analysis in PK, PK-based Design • Statistical Design and Analysis (3) • Noncompartmental Analysis in PK, PK-based Design
71	Munich	Apr 22	Bioequivalence workshop	• Statistical Design and Analysis (2)
74	Ljubljana	May 17–19	Bioequivalence and Bioavailability	• Successfully Overcoming Sample Size Challenges in BE Studies • Design and Evaluation of BE Studies: Over-view and Introduction • Analytical Development and Validation

Σ	Location	Date	Conference / Workshop / Training	Title (number)
		2010		
78	Ljubljana	May 17–19	Bioequivalence and Bioavailability	• Clinical Part of BA/BE Studies • Noncompartmental Analysis in PK, PK-based Design • Statistical Design and Analysis (2)
80	Nijmegen	Jun 17	Bioequivalence workshop	• Biostatistical Aspects of BE Studies • Sample Size Issues in BE Studies
82	Prague	Oct 14	Workshop on Bioanalytics for BE Studies	• Basics of Bioanalytics • Validation of Bioanalytical Methods
86	Munich	Oct 25–27	Bioequivalence and Bioavailability Studies	• Taking a Biostatistical Approach to Designing a BE Study: Ensuring Success through Effective Planning (3) • Sample Size Challenges in BE Studies and the Myth of Power
		2011		
92	Mumbai	Jan 29/30	Biostatistics: Basic concepts & applicable principles for various designs in BE studies and data analysis	• Background and History of BE • Basic Concepts • Basic Designs for BE Studies • Advanced Designs • Sample Size Calculations • Add-On and Sequential Designs
93	Barcelona	Feb 24	Revision of BE Requirements for Modified Release Products	• Assessment of bioequivalence of implants: Appropriate study design, metrics, and acceptance criteria
95	Budapest	May 16–18	Bioavailability / Bioequivalence and Dissolution Testing	• Design and Evaluation of BE Studies: Overview and Introduction • Noncompartmental Analysis in PK, PK based Design
98	Budapest	May 16–18	Bioavailability / Bioequivalence and Dissolution Testing	• Statistical Design and Analysis (2) • Determining Optimal Sample Size
99	Vienna	Jul 11	Workshop on GCP and Logistics for Bioequivalence Studies	• Theory and Practice
104	Aesch	Aug 8–10	Advanced Workshop on Bioequivalence	• Overview • Noncompartmental Analysis in PK, PK-based Design • Statistical Design and Analysis (2) • Determining Optimal Sample Size
107	Aesch	Aug 11–12	Workshop on Statistics for Bioanalysis and Bioequivalence	• Regression & Calibration • Basic Concepts of BE Basic Designs for BE Studies • Advanced Designs for BE Studies
110	Brussels	Sep 19–21	2nd Annual Bioequivalence and Bioavailability Studies	• Setting up a BE study: from design to approval • Power and intra-subject variability in two stage approaches • 'Perfecting' the two stage study design
111	Berlin	Nov 8	Innovations in Modified Release	• Practically meeting modified release BE requirements
		2012		
116	Mumbai	Jan 27–29	*In vitro in vivo* Correlation (*IVIV*C), Biowaivers & Statistical Aspects of Bioequivalence in Drug Product Development	• Design and Conduct of BE Studies and Current Regulatory Trends • Sample Size Calculations • Examples • Statistical aspects of two-way cross-over studies • Statistical aspects of reference-scaled studies

Σ	Location	Date	Conference / Workshop / Training	Title (number)
		2012		
124	Nyon	Mar 12	Seminar on BABE Studies	• Design and Conduct of BE Studies and Current Regulatory Trends • Clinical part of BA/BE studies • Specific designs (3) • Focus on PK topics currently being debated (2) • Ensuring bioanalytical compliance of BA/BE studies
129	Moscow	May 23–25	Advanced practical training on pharmacokinetics, statistics, and analytics in Bioequivalence Studies towards Russian regulatory requirements	• Introduction to Bioequivalence • PK-NCA, PK based Design, Biostatistics (2) • Development of Bioanalytical Methods for BE Studies • Validation of Bioanalytical Methods for BE Studies
130	Moscow	Oct 30	Drug development and registration: «Pharma-2020» Implementation Strategy	• Sample Size Estimation in BE Studies including Studies with Highly Variable Drugs – Comparison of Russian and EU Guidelines
131	Moscow	Oct 31	Statistics for Bioequivalence Studies	• Sample Size Estimation, Two-Stage Sequential Designs, Reference-scaling (HVDs / HVDPs)
133	Prague	Dec 13	Seminar on Bioequivalence Studies	• Bioequivalence Studies of Highly Variable Drugs / Drug Products (HVDs / HVDPs) • Statistics of Two Stage Study Designs
		2013		
136	Mumbai	Jan 25–27	Advanced concepts of *IVIVC* through case studies; biostatistical aspects of Reference-scaled & Two stage designs: A regulatory perspective	• Reference-Scaled Average Bioequivalence (HVDs / HVDPs) • RSABE (NTIDs) • Two-Stage Designs
140	Bucharest	Mar 19	Bioequivalence workshop	• Integration in Chromatography • Sample Size Estimation • Sequential Designs • Introduction to Population PK
141	Budapest	May 16	Bioavailability/Bioequivalence, Dissolution and Biowaivers	• Experiences in Implementing Two-Stage Designs in Europe: Tricks and Traps
143	Leuven	Jun 5/6	Bioequivalence Assessment of Oral Dosage Forms: Basic Concepts and Practical Applications	• Pharmacokinetic Analysis of BE Data • Statistical Analysis of BE Data
149	Ulm	Jul 18/19	Workshop in Biostatistics for Bioequivalence	• Introduction to Biostatistics • Statistical Basics of Bioequivalence • Sample Size Estimation • Adaptive Designs • Highly Variable Drugs / Drug Products • Group Effects in Bioequivalence
150	Amman	Sep 24	1st MENA Regulatory Conference on Bioequivalence, Biowaivers, Bioanalysis and Dissolution	• Pharmacokinetic and Statistical Analysis of BE Data
153	Prague	Oct 16	Clinical Development Workshop	• Partial AUCs • Two-Stage Designs in BE-Studies • Modified Release: $C_{min} - C_{\tau}$
157	Zagreb	Oct 23/24	Biostatistics workshop	• Introduction to Biostatistics • Statistical Basics of Bioequivalence • Sample Size Estimation • Adaptive Designs

Σ	Location	Date	Conference / Workshop / Training	Title (number)
		2012		
160	Zagreb	Oct 23/24	Biostatistics workshop	• Adaptive Designs • Highly Variable Drugs / Drug Products • Group Effects in Bioequivalence
		2014		
161	Munich	Apr 7	Haemophilia Master Class: Personalized Treatment and Care	• Pharmacokinetic Issues: A Basic Refresher
165	Moscow	Apr 24	Bioequivalence Studies in Russia: Pharmacokinetics, Statistics and Analytics	• Basic Designs for BE Studies • Sample Size Estimation for BE Studies • Two-Stage Sequential Designs • Outliers in BE Studies
166	Budapest	May 14	Bioavailability/Bioequivalence, Dissolution and Biowaivers	• Practical Advice for Implementing Two-Stage Designs
167	Frankfurt	Jul 3	Advisory Board on Haemophilia	• Pharmacokinetic Issues: A Basic Refresher
174	Barcelona	Sep 17/18	Design and Evaluation of Bioequivalence Studies	• Issues in Bioanalytical Method Validation (EMA vs. FDA) • Introduction to Biostatistics for Bioequivalence • Evaluation of Parallel and Cross-over Designs • Two-Stage Designs • Replicate Designs with Adaptation of Acceptance Criteria for HVDs / HVDPs • Some Ideas about Pilot Studies • Sample Size Estimation for BE Studies
		2015		
175	Barcelona	Jan 27	XII Congreso de la Sociedad Española de Farmacia Industrial y Galénica	• Two-Stage Sequential Designs in Bioequivalence
176	Munich	Jan 30	Interactive Workshop PK Dosing in Haemophilia A	• Pharmacokinetic Issues: A Basic Refresher
177	Prague	May 19	Bioavailability, Bioequivalence, Dissolution and Biowaivers	• Statistical Software for Bioequivalence
179	Kyiv	Nov 19	5th Scientific Conference “Clinical Trials of Medicines in Ukraine”	• Designs for Bioequivalence Studies • Sample Size Estimation for Bioequivalence Studies
		2016		
180	Bilbao	Mar 11	Drug Modeling & Consulting – Group Meeting	• Reference-Scaled Average Bioquivalence
181	Lisbon	Jun 6	Scientific and Regulatory Issues in Drug Development and Bioequivalence	• Statistical Planning and Evaluation of Bioequivalence Studies
182	Vienna	Jun 16	Pharmacometrics & Biostatistics Meeting	• Inflation of the Type I Error in Reference-scaled Average Bioequivalence
185	Prague	Sep 22	BioBridges 2016	• Two-Stage Sequential Designs (2) • Inflation of the Type I Error in Reference-scaled Average Bioequivalence
190	Moscow	Oct 6	BE Workshop	• Sample Size Estimation • Two Stage Designs • Reference-scaling • Software Validation • Case Studies
194	Berlin	Nov 14–16	Bioequivalence, Dissolution & IVIVC	• The General Requirements for Biostudies • Establishing the Biostudy Statistical Design (2) • The General Requirements for Biostudies

Σ	Location	Date	Conference / Workshop / Training	Title (number)
		2016		
198	Berlin	Nov 14–16	Bioequivalence, Dissolution & IVIVC	• Pilot Studies Similarity, Comparability and Correlation • Software Validation´ • General Hurdles and Pitfalls in BE Studies • Where are we going with Dissolution and BE Studies?
199	Prague	Dec 9	Zentiva	• Inflation of the Type I Error in Reference-scaled Average Bioequivalence
		2017		
207	Barcelona	Feb 20/21	Bioequivalence, Dissolution & IVIVC	• The General Requirements for Biostudies • Establishing the Biostudy Statistical Design (2) • Similarity, Comparability and Correlation • The Predictive Power of Dissolution and Alternatives to Full Bioequivalence • Validation and Compliance Issues • General Hurdles and Pitfalls in BE Studies • Where are we going with Dissolution and BE Studies?
215	Budapest	May 3/4	Course on Pharmacokinetics and Bioequivalence	• (L)ADME / Basics of Pharmacokinetics • PK and statistical background of BE studies • Clinical study design (5) • Regulatory requirements
223	Vienna	Jun 12–14	Bioequivalence, Dissolution & IVIVC	• The General Requirements for Biostudies • Establishing the Biostudy Statistical Design (2) • Similarity, Comparability and Correlation • The Predictive Power of Dissolution and Alternatives to Full Bioequivalence • Validation and Compliance Issues • General Hurdles and Pitfalls in BE Studies • Where are we going with Dissolution and BE Studies?
224	Prague	Sep 21	BioBridges 2017	• How to design a pilot study – extrapolation of results
228	Budapest	Oct 5	2nd Annual Biosimilars Forum	• Open Issues in the Assessment of Bioequivalence and Biosimilarity: Unequal carry-over – “solved” in BE but still an Issue in Assessing Biosimilarity? • Multi-Group and Multi-Site Studies. To pool or not to pool? • Group-Sequential and Two-Stage Designs • Reference-scaling and Control of the Type I Error
229	Yaroslavl	Oct 19/20	IInd International Conference «Studies of medicinal products: Simple and complex tasks»	• Multi-Group Studies in BE. To pool or not to pool?
233	Léon	Nov 20/21	Bioequivalence, Dissolution & IVIVC	• The General Requirements for Biostudies • Similarity, Comparability and Correlation • The Predictive Power of Dissolution and Alternatives to Full Bioequivalence • Validation and Compliance Issues
236	Kaunas	Dec 5/6	Training on Bioequivalence	• Bioanalytical Method Validation • Dissolution / Biowaivers / IVIVC • (L)ADME / Basics of PK / NCA

Σ	Location	Date	Conference / Workshop / Training	Title (number)
		2017		
243	Kaunas	Dec 5/6	Training on Bioequivalence	• Calculation of PK Metrics • The Concept of BA and BE • Types of Study Designs • Sample Size Estimation • Group-Sequential and Two-Stage Designs • Reference-scaling and Control of the Type I Error • Protocol & Report, Risks, Case Studies
		2018		
251	Barcelona	Mar 19–21	Bioequivalence, Dissolution & IVIVC	• The General Requirements for Biostudies • Establishing the Biostudy Statistical Design (2) • Similarity, Comparability and Correlation • The Predictive Power of Dissolution and Alternatives to Full Bioequivalence • Validation and Compliance Issues • General Hurdles and Pitfalls in BE Studies • Where are we going with Dissolution and BE Studies?
252	Vienna	Apr 6	Shire	• How to measure what happens in pharmacokinetics: PK metrics of relevance!
253	Amsterdam	Apr 12	3rd International Conference of the Global Bioequivalence Harmonisation Initiative	• Primary and secondary PK metrics for evaluation of steady state studies, C_{min} vs. C_{τ}, relevance of C_{min}/C_{τ} or fluctuation for BE assessment
259	Pamplona	Apr 24	Basic Statistical Concepts Behind BE Testing	• Basic Statistics for BE • Sample Size Estimation • Group-Sequential and Two-Stage Designs • Reference-scaling and Control of the Type I Error • Nonparametric Statistics (t_{max}, t_{lag}) • Special Topics
261	Oberursel	Jun 5/6	AGAH-Workshop “Introduction into Basic Principles of Pharmacokinetics”	• How to measure what happens in pharmacokinetics: PK metrics of relevance! • Pitfalls in BA/BE
262	Amman	Sep 24	3rd MENA Regulatory Conference On Bioequivalence, Biowaivers, Bioanalysis and Dissolution	• Multi-Group Studies in BE. To pool or not to pool?
263	Prague	Sep 26	BioBridges 2018	• Multi-Group Studies in BE. To pool or not to pool?
264	Budapest	Oct 26	3rd Annual Biosimilars Forum	• Roundtable Moderation
272	Athens	Nov 7–9	Bioequivalence, Dissolution & IVIVC	• The General Requirements for Biostudies • Establishing the Biostudy Statistical Design (2) • Similarity, Comparability and Correlation • The Predictive Power of Dissolution and Alternatives to Full Bioequivalence • Validation and Compliance Issues • General Hurdles and Pitfalls in BE Studies • Where are we going with Dissolution and BE Studies?
275	Gdańsk	Sep 3	Statistical Assessment of Bioequivalence Studies	• Design of Comparative BA Studies • Noncompartmental Analysis, Statistical Evaluation • Pitfalls in Bioequivalence

Σ	Location	Date	Conference / Workshop / Training	Title (number)
		2019		
276	Gdańsk	Sep 3	Statistical Assessment of Bioequivalence Studies	• Bioanalytical Method Development and Validation
284	Athens	Nov 4–6	Bioequivalence, Dissolution & IVIVC	• The General Requirements for Biostudies • Establishing the Biostudy Statistical Design (2) • Similarity, Comparability and Correlation • The Predictive Power of Dissolution and Alternatives to Full Bioequivalence • Validation and Compliance Issues • General Hurdles and Pitfalls in BE Studies • Where are we going with Dissolution and BE Studies?
		2020		
289	Campinas	Feb 11–13	Network of Scientific Excellence	• Steady-state Studies • Pilot Studies • Two-Stage Designs • Replicate Designs • Outliers in BE
		2021		
290	São Paulo	Apr 29	Seminário Internacional: Estudos em doses múltiplas para medicamentos genéricos e similares de liberação modificada – Contexto nacional e internacional	• Steady-State Studies: Scientific Background, Regulatory Requirements, Current Discussions / Open Issues
291	Vienna	Oct 1	Takeda	• Bioequivalence. An Old Area with some Uncharted Territories
295	Bilbao	Oct 18	BE course	• Biostudy Statistical Design and Evaluation (3) • General Hurdles and Pitfalls in BE Studies
296	Yaroslavl	Oct 22	3rd International Conference «Studies of medicinal products: Simple and complex tasks»	• Critical Remarks on Reference-Scaled Average Bioequivalence
297	Vienna	Dec 15	Biometric Colloquium of the Viennese Section of the IBS	• Bioequivalence. An Old Area with some Uncharted Territories
		2022		
298	Prague	Sep 23	BioBridges 2022	• t_{max} Evaluation: Where are we and where will we go…
299	Amsterdam	Sep 28	5th International Workshop of the Global Bioequivalence Harmonisation Initiative	• Novel approaches in adaptive designs and α adjustment, e.g., with futility criteria and for parallel design studies
301	Oberursel	Oct 6/7	AGAH-Workshop “Introduction into Basic Principles of Pharmacokinetics”	• How to measure what happens in pharmacokinetics: PK metrics of relevance! • Pitfalls in BA/BE
		2023		
302	Brussels	Apr 26	2nd Bioequivalence Workshop	• Statistical challenges and opportunities in ICH M13A
303	Prague	Sep 21	BioBridges 2023	• Sex- and group-related problems in BE. A delusion.
305	Oberursel	Oct 5/6	AGAH-Workshop “Introduction into Basic Principles of Pharmacokinetics”	• How to measure what happens in pharmacokinetics: PK metrics of relevance! • Pitfalls in BA/BE
306	Frankfurt	Oct 11	Experience meets Expertise. BE: New Trends and recent Discussions.	• ICH M13A: Testing for multi-group and multi-center effects in bioequivalence. Statistical considerations and consequences for interpretation.

Σ	Location	Date	Conference / Workshop / Training	Title (number)
		2024		
307	Brussels	Nov 29	Medicines for Europe. BE Working Group meeting	• Data Manipulation in Bioequivalence
308	Rockville	Apr 16	6th International Workshop of the Global Bioequivalence Harmonisation Initiative	• Highly Variable Drugs and Type I Error
309	Rockville	Jun 13	Spring Workshop on Data Integrity in Bioequivalence Studies	• Data Manipulation in Bioequivalence
311	Oberursel	Oct 1/2	AGAH-Workshop "Introduction into Basic Principles of Pharmacokinetics"	• How to measure what happens in pharmacokinetics: PK metrics of relevance! • Pitfalls in BA/BE
312	Vienna	Nov 12	Medical University Vienna, Department of Clinical Pharmacology	• Comparative BA Studies – Fundamentals and Common Pitfalls
		2025		
313	Amsterdam	Feb 26	3rd Bioequivalence Conference	• Statistical challenges and opportunities in ICH M13C
317	Novo mesto	May 12/13	Challenges in Pharmacokinetic and Statistical Analyses in Bioequivalence	• BE designs – higher order, replicate and parallel • Pilot studies • Multi-group studies • PK and statistical analyses of BE studies – special topics
318	Rockville	Jun 11	Spring Workshop on Statistical and Data Analysis Issues and Solutions for ANDAs and 505(b)(2) NDAs	• Group-by-Treatment Interaction Effects in Comparative BA Studies – A Myth or Reality?
321	Oberursel	Oct 7/8	AGAH-Workshop "Introduction into basic principles of clinical pharmacokinetics"	• How to measure what happens in pharmacokinetics: PK metrics of relevance! • Pitfalls in BA/BE • Some PK mysteries unveiled

IT Proficiency

Networks	LanManager (Hewlett-Packard, Microsoft), Samba (GNU)
LIMS	LAB/UX (Hewlett-Packard / Agilent Technologies)
Operating Systems	HP/UX (Hewlett-Packard), DOS (Microsoft, Digital Research), OS/2 (IBM), Windows XP | Vista | 7 | 11 (Microsoft)
GUIs	CDE (The Open Group), Windows 3.11 for Workgroups | NT4 | 2000 (Microsoft)
Scripts, Macros	awk (Unix), BAT (Microsoft), JavaScript (Sun)
Office	Microsoft, Apache Software Foundation
Languages	Pascal for Workstations (Hewlett-Packard), TurboPascal (Borland), BASIC dialects: Rocky Mountain Basic (Hewlett-Packard), HTB (TransEra), GW-Basic | QuickBASIC/VBA (Microsoft), CRA-Basic (Shimadzu)
Databases	dBase (Ashton-Tate), ACCESS (Microsoft), MySQL (Oracle)
Web	(X)HTML | CSS (W3C), php (The PHP Group), APACHE (Apache Software Foundation)
Software	• Proprietary BioEvaluat (Biokinet), TopFit (Springer), STATISTICA (StatSoft), StatXact (Cyxel), NCSS (NCSS Software), StudySize | Result (CreoSoft), EquivTest | PK (Statistical Solutions), Kinetica (Thermo Scientific), Phoenix WinNonlin | NLME | IVIVC (Certara), Monolix | PKanalix | Simulix (Lixoft) • Open source BIOEQV (Wijnand), Boomer (Bourne), WinSAAM (WinSAAM Inc), MONOLIX (The Monolix Group), Berkley Madonna (Macey & Oster), WinBUGS | PKBugs (GNU), Octave (GNU), MikTeX (Schenk), git (GNU), pandoc (GNU), GitHub (Microsoft), R (The R Foundation for Statistical Computing)

Packages

1 Schütz H. AdaptiveBE: Acceptability of Adaptive Bioequivalence Studies. 2018-05-07; Package version 0.8.4.9000. https://github.com/Helmut01/AdaptiveBE
2 Molins E, Labes D, Schütz H, Ocaña J. betsd: Adjusting significance levels in two-stage adaptive 2×2 crossover designs. 2019-07-03; Package version 0.1.5. https://github.com/eduard-molins/betsd
3 Schütz H. indirectBE: Adjusted Indirect Comparisons. 2021-06-11; Package version 0.3.0.
4 Labes D, Lang B, Schütz H. Power2Stage: Power and Sample-Size Distribution of 2-Stage Bioequivalence Studies. 2021-11-12; Package version 0.5-4. https://doi.org/10.32614/CRAN.package.Power2Stage
5 Schütz H, Tomashevskiy M, Labes D. replicateBE: Average Bioequivalence with Expanding Limits (ABEL). 2022-05-02; Package version 1.1.1. https://doi.org/10.32614/CRAN.package.replicateBE
6 Labes D, Schütz H, Lang B. PowerTOST: Power and Sample Size Based on Two One-Sided *t*-Tests (TOST) for (Bio)Equivalence Studies. 2025-09-23; Package version 1.5-7. https://doi.org/10.32614/CRAN.package.PowerTOST

Posters

#	Location	Date	Occasion	Title	Co-authors
1	Uppsala	Oct 26, 1988	International Symposium on Coupled Column Separations	Development and Application of an HPLC Determination of Buspirone in Plasma by Solid-Phase Extraction and On-Line Precolumn Trace Enrichment	Eichinger A, Nitsche V
2	Vienna	Jan 23–25, 1989	6. Forum Analytik	Anwendung von Säulenschaltungen in der HPC anhand von Beispielen	Eichinger A, Nitsche V
3	Graz	Oct 26–28, 1989	VIII. Wissenschaftliche Tagung der Österreichischen Pharmazeutischen Gesellschaft	Spurenanalytik von Arzneistoffen aus biologischen Matrices	Eichinger A, Nitsche V
4	Geneva	Apr 17–19, 1990	4th European Congress of Biopharmaceutics and Pharmacokinetics	Determination of buspirone in plasma by HPLC with solid-phase extraction and on-line precolumn trace enrichment and its application to a pharmacokinetic study	Eichinger A, Nitsche V
5	Geneva	Apr 17–19, 1990	4th European Congress of Biopharmaceutics and Pharmacokinetics	Determination of amoxicillin and ampicillin using a new HPLC method with post-column derivatization and its application to bioavailability studies	Eichinger A, Nitsche V
6	Vienna	Jan 25–27, 1993	10. Forum Analytik	Implementierung der GLP in einem Auftragsforschungslabor mit 6 Mitarbeitern	Eichinger A, Krenauer J, Kaspar A, Wolf C, Nitsche V
7	San Antonio	Nov 10–14, 2013	AAPS Annual Meeting and Exposition	Performing Reference-Scaled Average Bioequivalence (RSABE) in Phoenix® WinNonlin® doi:10.13140/RG.2.1.1008.0800	Henry A, Hughes L, Davis S
8	Vienna	Aug 24–28, 2014	35th Annual Conference of the International Society for Clinical Biostatistics	Adaptive two-stage bioequivalence trials with early stopping and sample size re-estimation doi:10.13140/RG.2.1.5190.0967	König F, Wolfsegger MJ, Jaki T, Wassmer G
9	Glasgow	Nov 16/17, 2015	3rd International Clinical Trials Methodology Conference	Adaptive two-stage bioequivalence trials with early stopping and sample size re-estimation doi:10.1186/1745-6215-16-S2-P218	König F, Wolfsegger MJ, Jaki T, Wassmer G

#	Location	Date	Occasion	Title	Co-authors
10	Berlin	Jul 8–13, 2017	XXVI Congress of the International Society on Thrombosis and Haemostasis and 63rd Annual Scientific and Standardization Committee Meeting	An investigation of the minimum half-life extension needed to make a clinically meaningful impact on dosing frequency of extended half-life recombinant FVIII products	Booth J, Steinitz-Trost K, Lee HY, Bauer A, Wolfsegger M
11	Sydney	Oct 29–Nov 1, 2017	HAA Annual Scientific Meeting	Minimum half-life extension ratio model for reduced dosing frequency of extended half-life recombinant FVIII products	Booth J, Steinitz-Trost K, Lee HY, Bauer A, Wolfsegger M
12	San Diego	Nov 12–16, 2017	AAPS Annual Meeting and Exposition	Reference-Scaled Average Bioequivalence (RSABE) Approach For Compounds With A Narrow Therapeutic Index (NTID) Using Phoenix™ WinNonlin®	Mehl C, Henry A, Hughes L
13	Vienna	Feb 20–23, 2018	62nd Annual Meeting of the Society of Thrombosis and Haemostasis Research	A Model of the Minimum Half-life Extension Ratio Needed to Reduce the Dosing Frequency of Extended Half-life (EHL) Recombinant FVIII (rFVIII) Products	Booth J, Steinitz-Trost K, Lee HY, Bauer A, Wolfsegger M
14	London	Dec 18–20, 2018	Pharmacology 2018	Assurance (expected power) for planning crossover bioequivalence trials doi:10.1111/bcp.13937	Ring A, Lang B, Kazaroho C, Labes D, Awounvo JS

Publications

1 Nitsche V, Mascher H, Schütz H. Comparative bioavailability of several phenytoin preparations marketed in Austria. Int J Clin Pharmacol Ther Toxicol. 1984; 22(2): 104–7. https://www.ncbi.nlm.nih.gov/pubmed/6698663.

2 Mascher H, Nitsche V, Schütz H. Separation, Isolation and Identification of Optical Isomeres of 1,4-Benzodiazepine Glucuronides from Biological Fluids by Reversed-Phase High-Performance Liquid Chromatography. J Chromatogr Biomed Appl. 1984; 306: 231–9. https://doi.org/10.1016/S0378-4347(00)80885-3.

3 Nitsche V, Mascher H, Schütz H. Bioverfügbarkeit von Amilorid-Hydrochlorothiazid-Kombinationspräparaten. Therapiewoche. 1985; 36(1): 56–60.

4 Nitsche V, Schütz H, Eichinger A. Rapid high-performance liquid chromatographic determination of nifedipine in plasma with on-line precolumn solid-phase extraction. J Chromatogr, Biomed Appl. 1987; 420: 207–11. https://doi.org/10.1016/0378-4347(87)80175-5.

5 Nitsche V, Lauschner R, Eichinger A, Schütz H. Absolute Bioverfügbarkeit von Ambroxol-Zäpfchen. Pharm Ztg. 1988; 133(32): 28–33.

6 Schütz H, Eichinger A, Nitsche V, Hofmann R. Relative bioavailability of 3 different chlormezanone 200 mg preparations after single dose oral administration. Int J Clin Pharmacol Ther. 1997; 35(3): 112–6. https://www.ncbi.nlm.nih.gov/pubmed/9089000.

7 Bohner H, Janiak PS, Nitsche V, Eichinger A, Schütz H. Relative bioavailability of different butamirate citrate preparations after single dose oral administration to 18 healthy volunteers. Int J Clin Pharmacol Ther. 1997; 35(3): 117–22. https://www.ncbi.nlm.nih.gov/pubmed/9089001.

8 Schütz H. An extremely strange observation*?* [letter]. Eur J Drug Metabol Pharmacokinet. 2004; 29(1): 69–71. https://doi.org/10.1007/BF03190576.

9 Fischer R, Schütz H, Grossmann M, Leis HJ, Ammer R. Bioequivalence of methylphenidate hydrochloride of an extended release preparation; comparison of an intact capsule and an opened capsule sprinkled on applesauce. Int J Clin Pharmacol Ther. 2006; 44(3): 135–41. https://doi.org/10.5414/cpp44135.

10 Schütz H, Fischer R, Grossmann M, Mazur D, Leis HJ, Ammer R. Lack of bioequivalence between two methylphenidate extended modified release formulations in healthy volunteers. Int J Clin Pharmacol Ther. 2009; 47(12): 761–9. https://doi.org/10.5414/cpp47761.

11 Leis HJ, Schütz H, Windischhofer W. Quantitative determination of methylphenidate in plasma by gas chromatography negative ion chemical ionisation mass spectrometry using *o*-(pentafluorobenzyloxycarbonyl)-benzoyl derivatives. Anal Bioanal Chem. 2011; 400(8): 2663–70. https://doi.org/10.1007/s00216-011-5048-6.

12 Schütz H, Labes D, Fuglsang A. Reference Datasets for 2-Treatment, 2-Sequence, 2-Period Bioequivalence Studies. AAPS J. 2014; 16(6): 1292–7. https://doi.org/10.1208/s12248-014-9661-0.
PMC https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4389751/pdf/12248_2014_Article_9661.pdf.
13 Roudier B, Davit B, Schütz H, Cardot J-M. Impact of Data Base Structure in a Successful In Vitro-In Vivo Correlation for Pharmaceutical Products. AAPS J. 2015; 17(1): 24–34. https://doi.org/10.1208/s12248-014-9680-x.
PMC https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4287291/pdf/12248_2014_Article_9680.pdf.
14 Schütz H. Two-stage designs in bioequivalence trials. Eur J Clin Pharmacol. 2015; 71(3): 271–81. https://doi.org/10.1007/s00228-015-1806-2.
15 Fuglsang A, Schütz H, Labes D. Reference Datasets for Bioequivalence Trials in a Two-Group Parallel Design. AAPS J. 2015; 17(2): 400–4. https://doi.org/10.1208/s12248-014-9704-6.
PMC https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4365103/pdf/12248_2014_Article_9704.pdf.
16 Labes D, Schütz H. Inflation of Type I Error in the Evaluation of Scaled Average Bioequivalence, and a Method for its Control. Pharm Res. 2016; 33(11): 2805–14. https://doi.org/10.1007/s11095-016-2006-1.
17 Cardot J-M, Roudier B, Schütz H. Dissolution comparisons using a Multivariate Statistical Distance (MSD) test and a comparison of various approaches for calculating the measurements of dissolution profile comparison. AAPS J. 2017; 19(4): 1091–1101. https://doi.org/10.1208/s12248-017-0063-y.
18 Hermans C, Mahlangu J, Booth J, Schütz H, Santagostino E, Young G, Lee H-J, Steinitz-Trost KN, Blanchette V, Berntorp E. Pharmacokinetic modelling and validation of the half-life extension needed to reduce the burden of infusions compared with standard factor VIII. Haemophilia. 2018; 24(3): 376–84. https://doi.org/10.1111/hae.13483.
19 Ring A, Lang B, Kazaroho C, Labes D, Schall R, Schütz H. Sample size determination in bioequivalence studies using statistical assurance. Br J Clin Pharmacol. 2019; 85(10): 2369–77. https://doi.org/10.1111/bcp.14055.
PMC https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6783617/pdf/BCP-85-2369.pdf.
20 Schütz H, Tomashevskiy M, Labes D, Shitova A, González-de la Parra M, Fuglsang A. Reference Datasets for Studies in a Replicate Design intended for Average Bioequivalence with Expanding Limits. AAPS J. 2020; 22(2): 44. https://doi.org/10.1208/s12248-020-0427-6.
21 Molins E, Labes D, Schütz H, Cobo E, Ocaña J. An iterative method to protect the type I error rate in bioequivalence studies under two-stage adaptive 2×2 crossover designs. Biom J. 2021; 63(1): 122–33.
https://doi.org/10.1002/bimj.201900388.
Pearls of Bioequivalence Award 2022 by »The Frankfurt Foundation Quality of Medicines« and the EUFEPS »Network Bioavailability and Biopharmaceutics«
22 Wolfsegger MJ, Bauer A, Labes D, Schütz H, Vonk R, Lang B, Lehr S, Jaki TF, Engl W, Hale MD. Assessing goodness-of-fit for evaluation of dose-proportionality. Pharm Stat. 2021; 20(2): 272–81. https://doi.org/10.1002/pst.2074.
23 Schütz H, Labes D, Wolfsegger MJ. Critical Remarks on Reference-Scaled Average Bioequivalence. J Pharm Pharmaceut Sci. 2022; 25: 285–96. https://doi.org/10.18433/jpps32892.
24 Uebel-von Sandersleben H, Mayer A, Ruhmann M, Dangel O, Schütz H. Pharmacokinetics of a Modified-Release Dexamphetamine Sulfate Formulation Following Single and Multiple Dosing in Healthy Adults: Comparative Bioavailability with Immediate-Release Dexamphetamine Sulfate, between Strengths, Assessment of Food and Meal Composition Effects. Scand J Child Adolesc Psychiatr Psychol. 2023; 11: 132–42. https://doi.org/10.2478/sjcapp-2023-0014.
25 Schütz H, Burger DA, Cobo E, Dubins D, Farkás T, Labes D, Lang B, Ocaña J, Ring A, Shitova A, Stus V, Tomashevskiy M. Group-by-Treatment Interaction Effects in Comparative Bioavailability Studies. AAPS J. 2024; 26(3): 50. https://doi.org/10.1208/s12248-024-00921-x.
26 Schütz H, Burger DA, Cobo E, Dubins D, Farkás T, Labes D, Lang B, Ocaña J, Ring A, Shitova A, Stus V, Tomashevskiy M. Rejoinder to the 'Letter to the Editor' on "Group-by-Treatment Interaction Effects in Comparative Bioavailability Studies". AAPS J. 2025; 27(1): 14. https://doi.org/10.1208/s12248-024-01008-3.
27 Osuchowski MF, Adamik H, Gozdzik W, Mascher D, Redl H, Winkler MS, Schütz H, Mascher H. The novel biomarker t^6A accurately detected septic patients and animals in the early stage of the disease but failed to predict outcome. Critical Care. 2025; 29:129. https://doi.org/10.1186/s13054-025-05354-2.
28 Wolfsegger MJ, Xu P, Cotterill A, Schütz H, Jaki TF. Paired and AB/BA Cross-over Design in Early Phase Clinical Trials: A Closer Look at Within-Subject Variance Bias. Pharm Stat. 2026; 25(2): e70088. https://doi.org/10.1002/pst.70088.
29 Schütz H (2026). Sex-by-Treatment Interaction in Comparative Bioavailability Studies. Manuscript in preparation.

Professional Activities

Jul 1976	Vinzenz Wagner GmbH (internship)	• Rheology, pycnometry, colorimetry
Jul 1977	Technol GmbH (internship)	• Rheology, flashpoint determination, pH measurement, UV/VIS spectrometry, IR spectrometry, normal phase HPLC

Jan 1980 – Oct 1980	Gerot Pharmazeutika GmbH	• Syntheses of NCEs (beta blockers, benzodiazepines)
Nov 1980 – Jan 1984	Pharmakologische Untersuchungsgesellschaft mbH	• Trace analysis of drugs in biological matrices (GC / HPLC) • Development and validation of software for PK, NCA, comparative BA • Evaluation of Phase I studies
Feb 1984 – May 1987	Biokinet GmbH	• Manager of the Analytical Laboratory • Development and validation of bioanalytical methods for the determination of drugs in biological matrices
Jun 1987 – Jul 2004	Biokinet GmbH	• Design, implementation, administration of a Laboratory Information Management System according to the rules of Good Automated Laboratory Practices • Manager of the Department of Biostatistics and Data Management • Design and evaluation of more than 500 comparative BA studies • Assessment of about 50 Phase I studies of external CROs
Oct 2004 – current	BEBAC – Consultancy Services for Bioequivalence and Bioavailability Studies	• Consultant in the domain of bioavailability and bioequivalence • Biostatistical services (design, evaluation, and assessment of studies) • Workshops, trainings • Support at regulatory meetings • Maintainer of the Bioequivalence and Bioavailability Forum
Feb 2022 – current	Lecturer at the Center for Medical Data Science, Medical University of Vienna	
2004 – current	Peer reviewer AAPS J, Chemometr Intell Lab Syst, Clin Pharmacokinet, Clin Res Regul Aff, Comput Meth Prog Biomed, Curr Drug Metab, Drug Metab Lett, Drugs in R&D, Eur J Clin Pharmacol, Eur J Pharm Biopharm, Eur J Pharm Sci, J Bioequivalence Bioavailab, J Biopharm Stat, J Pharm Pharmacol, J Pharmacokinet Pharmacodyn, Pharm Res, Pharm Stat, Stat Med, Ther Innov Regul Sci	
2015 – current	Member of the Editorial Board of 'Drugs in R&D'	
2016 – current	Co-organizer of the 'BioBridges' Conference at the Institute of Pharmacology, 1st Faculty of Medicine, Charles University, Prague	

Professional Memberships

1992 – 2014	Drug Information Association (DIA)
2004 – current	Austrian Association of Consulting Engineers
2005 – current	Region Austria-Switzerland of the International Biometric Society (ROeS-IBS)
2005 – current	Austrian Pharmaceutical Association (ÖPhG)
2005 – current	European Network for Business and Industrial Statistics (ENBIS)
2008 – current	International Society for Clinical Biostatistics (ISCB)
2010 – current	Fédération internationale pharmaceutique (FIP)
2014 – current	American Association of Pharmaceutical Scientists (AAPS)
2015 – current	European Federation for Pharmaceutical Sciences (EUFEPS)
2018 – current	Association for Applied Human Pharmacology (AGAH)

Certifications

Apr 1980 – current	CMAS	Diver *
Jul 1981 – current	PADI	Open Water Scuba Diver
May 1989 – current		Advanced Open Water Diver
Jun 1989 – current		Rescue Diver
Jul 1995 – Dec 1995		Divemaster
Aug 1995 – Dec 2005		Open Water Scuba Instructor
May 1997 – current	NACD	Cave Diver
Feb 2002 – current	ProNRC	Nitrox Level I
		Nitrox Level II