



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
helmut.schuetz@chello.at (private)

Personal Details

Nationality: Austrian

Education

- | | |
|----------------|---|
| 1973 – 1979 | Higher Federal Education and Research Institute for the Chemical Industry
<i>Vienna, Austria</i>
Focus: Technical Chemistry, final examination passed with distinction
Standesbezeichnung „Ingenieur“ (Professional Designation ‘Engineer’) |
| 1983 | |
| 2023 – current | Faculty of Pharmacy, Universidade de Lisboa
<i>Lisbon, Portugal</i>
PhD candidate |

Language Skills

Native German, fluent in spoken and written English. Τραυλίζει στα ελληνικά. LATINAE IAM OBLITUS EST

Activities

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| 1980 | Gerot Pharmazeutika GesmbH
<i>Vienna, Austria</i>
Syntheses of NCEs (beta blockers, benzodiazepines) |
| 1980 – 1984 | Pharmakologische Untersuchungsgesellschaft mbH
<i>Vienna, Austria</i>
Trace analysis (GC/HPLC)
Development of software, evaluation of Phase I studies |
| 1984 – 2004 | Biokinet GmbH
<i>Vienna, Austria</i> |
| 1984 – 1987 | Manager of the Analytical Laboratory
Development and validation of bioanalytical methods for the determination of drugs in biological matrices |
| 1987 – 2004 | Manager of the Department of Biostatistics and Data Management
Design, implementation, administration of a Laboratory Information Management System (LIMS) according to the rules of GALP (Good Automated Laboratory Practices)
Design and evaluation of more than 500 comparative BA studies
Assessment of about 50 Phase I studies of external Contract Research Organizations (CROs) |
| 2004 – current | BEBAC – Consultancy Services for Bioequivalence and Bioavailability Studies
<i>Vienna, Austria</i>
Independent Consultant in the domain of bioavailability and bioequivalence studies
Biostatistical services (design, evaluation, and assessment of studies; lectures, workshops)
Support at regulatory meetings
Maintainer of the Bioequivalence and Bioavailability Forum
Co-organizer of the BioBridges workshop series |
| 2016 – current | |
| 2022 – current | Center for Medical Data Science, Medical University of Vienna
Lecturer |

Memberships

1992 – 2014	DIA	Drug Information Association
2004 +	WKO	Wirtschaftskammer Österreichs (The Austrian Federal Economic Chamber)
2004 +	FI	Fachverband Ingenieurbüros (Austrian Association of Consulting Engineers)
2005 +	ROeS	Region Austria-Switzerland of the IBS (International Biometric Society)
2005 +	ÖPhG	Österreichische Pharmazeutische Gesellschaft (Austrian Pharmaceutical Association)
2005 +	ENBIS	European Network for Business and Industrial Statistics
2008 +	ISCB	International Society for Clinical Biostatistics
2010 +	FIP	Fédération internationale pharmaceutique (International Pharmaceutical Federation)
2014 +	AAPS	American Association of Pharmaceutical Scientists
2015 +	EUFEPS	European Federation for Pharmaceutical Sciences
2018 +	AGAH	Arbeitsgemeinschaft für Angewandte Humanpharmakologie (Association for Applied Human Pharmacology)
2015 +		Editorial Board of <i>Drugs in R&D</i>

Presentations / Continuing Education

1980		Introduction to Multidimensional Gas Chromatography (Vienna )
1982		Rocky Mountain BASIC I/9000 (Vienna )
		Derivatization in GC (Vienna )
		Analysis of illicit drugs (Vienna )
1984		Symposium on Sample Preparation and Isolation Techniques using Bonded Silica (Vienna )
1985		Biogenic amines and their metabolites (Vienna )
1987		Bioavailability/Bioequivalence, Pharmaceutical and Therapeutic Equivalence (Würzburg )
		3 rd European Congress of Biopharmaceutics and Pharmacokinetics (Freiburg )
		Pascal Operating System for HP9000 Series 200/300 (Vienna )
		Programming in Pascal (Vienna )
1988		5. Forum Analytik (Vienna )
		International Symposium on Coupled Column Separation (Uppsala )
1989		6. Forum Analytik (Vienna )
		VIII. Scientific Meeting of the Austrian Pharmaceutical Association (Graz )
1990		Background – Design – Analysis & Interpretation of Bioavailability / Bioequivalence Studies (London )
		4 th European Congress of Biopharmaceutics and Pharmacokinetics (Geneva )
		Bioavailability of Drugs & Pharmacokinetics (Amsterdam )
		Modern Methods for Drug Monitoring and their Significance for Clinical Practice (Graz )
		Analytical Methods Validation: Bioavailability, Bioequivalence and Pharmacokinetic Studies Conference (Arlington )
1991		8. Forum Analytik (Vienna )
		Workshop in Pharmacokinetic Modeling (Palo Alto )
		Workshop in Bioavailability/Bioequivalence (Palo Alto )
1992		9. Forum Analytik (Vienna )
		LIMS Workshop (Linz )
		Supercritical Fluid Extraction Workshop (Vienna )
		International Open Conference on Dissolution, Bioavailability, Bioequivalence (Toronto )
		Oral Modified-Release Dosage Forms: Biopharmaceutical Challenges and Clinical Implications (Stockholm )
		Quality Assurance in the Analytical Laboratory (Vienna )
		Modified Release Formulations in Clinical Practice, Pharmaceutical Technology and Registration (Graz )
		Millennium 2010 Chromatography Manager (Vienna )
		GLP Module: Good Laboratory Practice, Basic Training (Bingen )
1993		10. Forum Analytik (Vienna )
		Shimadzu HPLC (Vienna )
		Computerized Data Handling – Current Trends in Pharmaceutical and Clinical Research (Neu-Ulm )
		Chromatography Meeting (Vienna )
		5 th European Congress of Biopharmaceutics and Pharmacokinetics (Brussels )
		HPLC Seminar for Professionals (Korneuburg )

- 1993 The Main Issue is Significance – Typical Pitfalls in Clinical Trials (Frankfurt )
- 1994 Generics in Comparison: Bioavailability, Bioequivalence (Vienna )
 HP-UX System Administration (Vienna )
 Bio-International Conference (Munich )
 Introduction to LAB / UX 2.0 LIMS (Vienna )
- 1995 Microsoft BackOffice (Vienna )
 BIOKINET 95: Kriterien der Bioäquivalenz (Vienna )
 2nd EUFEPS Nuremberg Conference: Symposium on Quality and Interchangeability of Topical Products for Local Action (Nuremberg )
- 1996 BIOKINET 96: Aktuelle Entwicklungen bei der Prüfung topischer Arzneimittel mit lokaler Wirkung (Vienna )
 HP-Focus „ErfolgsAnalysen“ (Vienna )
- 1997 Clinical Research Seminar Series: Biometrics in Europe (Munich )
- 1999 The Path of a Drug through the Body: Bioavailability – Pharmacokinetics (Vienna )
 Bio-International Conference (London )
- 2001 Ethical considerations in clinical trials (London )
- 2002 International Symposium On Scientific and Regulatory Aspects of Dissolution and Bioequivalence (Athens )
- 2003 Bio-International Conference (London )
- 2004 Dissolution Testing, Bioequivalence & Bioavailability Studies: Maximizing Scientific and Technological Advancements ( Brussels)
- 2005 Dissolution, Bioavailability & Bioequivalence: Finding Alternatives to BA/BE Testing (Amsterdam )
 Bio-International Conference (London )
- 2006 Dissolution Testing, Bioavailability & Bioequivalence (Budapest )
 Conference on BA/BE (Athens )
 International Regulatory Workshop on Bioequivalence and Dissolution (Budapest )
- 2007 Dissolution Testing, Bioavailability & Bioequivalence (Budapest , Berlin )
 EGA Workshop on Bioequivalence Study Design, Working to GCP and Interpreting the Guidelines (Lisbon )
- 2008 Dissolution, Bioavailability and Bioequivalence (Budapest , Prague )
 New Regulations in Bioequivalence: Revised European CHMP Note for Guidance (Bad Homburg )
 Dissolution Testing, Bioequivalence and Bioavailability Strategies (London )
 Increasing Predictability in Gastrointestinal Simulation (Zeist )
 2nd World Conference on Magic Bullets – Ehrlich II (Nuremberg )
 CMD(h)-EGA Symposium on Bioequivalence (Paris )
 Bio-International Conference (London )
 Bioavailability, Bioequivalence, Pharmacokinetics & Beyond (Ahmedabad )
- 2009 EUFEPS BABP Open Discussion Forum (Bonn )
 Bioequivalence and Bioavailability (Budapest )
 Introduction to Phoenix WinNonlin 6.0 (Munich )
- 2010 Hurdles and Pitfalls in Generic Drug Development (Berlin )
 EBF & EUFEPS Workshop: EMEA Draft Guideline on Validation of Bioanalytical Methods (Brussels )
 Bioequivalence and Bioavailability (Ljubljana )
 3rd CMD(h)-EGA Symposium on Bioequivalence (London )
 2nd International Regulatory Workshop on Bioequivalence, Bioanalysis, Dissolution and Biosimilarity (Budapest )
 Bioequivalence and Bioavailability Studies (Munich )
- 2011 Biostatistics: Basic concepts & applicable principles for various designs in bioequivalence studies and data analysis (Mumbai )
 EUFEPS BABP Open Discussion Forum (Barcelona )
 Bioavailability/Bioequivalence and Dissolution Testing (Budapest )
 International Symposium on BA/BE of Oral Drug Products (Kobe )
 2nd Annual Bioequivalence and Bioavailability Studies (Brussels )
 Innovations in Modified Release (Berlin )

- 2012 *In vitro in vivo* Correlation (*IVIVC*), Biowaivers & Statistical Aspects of Bioequivalence in Drug Product Development (Mumbai 🇮🇳)
Drug development and registration «Pharma-2020» Implementation Strategy (Moscow 🇷🇺)
3rd International Regulatory Workshop on Bioequivalence, Bioanalysis, Dissolution and Bio-similarity (Budapest 🇮🇳)
- 2013 Advanced concepts of *IVIVC* through case studies; Biostatistical aspects of Reference-scaled & Two stage designs (Mumbai 🇮🇳)
Bioavailability / Bioequivalence, Dissolution and Biowaivers (Budapest 🇮🇳)
Bioequivalence Assessment of Oral Dosage Forms (Leuven 🇧🇪)
EUFEPS BABP Open Discussion Forum on the Revised European Guideline on Pharmacokinetic and Clinical Evaluation of Modified Release Dosage Forms (Bonn 🇩🇪)
1st MENA Regulatory Conference on Bioequivalence, Biowaiver, Bioanalysis and Dissolution (Amman 🇮🇪)
5th BBBB International Conference. From Drug Discovery and Formulation Strategies to Pharmacokinetics and Pharmacodynamics (Athens 🇬🇷)
Clinical Development Workshop (Prague 🇨🇪)
International Regulatory Workshop on Bioequivalence, Bioanalysis, Dissolution and Bio-similarity (Budapest 🇮🇳)
- 2014 Haemophilia Master Class: Personalized Treatment and Care (Munich 🇩🇪, Frankfurt 🇩🇪)
EMA / EGA joint workshop on the impact of the revised EMA Guideline on the Pharmacokinetic and Clinical Evaluation of Modified Release Dosage Forms (London 🇬🇧)
Introduction to Phoenix[®] for WinNonlin[®] Version 6.2.x & 6.3 (Munich 🇩🇪)
Bioequivalence Studies in Russia: Pharmacokinetics, Statistics and Analytics (Moscow 🇷🇺)
Bioavailability / Bioequivalence, Dissolution and Biowaivers (Budapest 🇮🇳)
4th International Regulatory Workshop on Bioequivalence and Dissolution (Budapest 🇮🇳)
Innovative Statistical Approaches in Drug Development (Vienna 🇦🇹)
- 2015 XII Congress of the Spanish Society of Pharmaceutical Technology (Barcelona 🇪🇸)
Interaktiver Workshop PK-Dosing in der Häemophilie A (Munich 🇩🇪)
1st Workshop of the Global Bioequivalence Harmonisation Initiative (Amsterdam 🇳🇱)
Joint workshop on the impact of the revised EMA Guideline on the Pharmacokinetic and Clinical Evaluation of Modified Release Dosage Forms (London 🇬🇧)
Bioavailability / Bioequivalence, Dissolution and Biowaivers (Prague 🇨🇪)
International Conference on Advances in the Area of Bioequivalence (Budapest 🇮🇳)
5th Scientific Conference «Clinical Trials of Medicines in Ukraine» (Kyiv 🇺🇦)
- 2016 Scientific and Regulatory Issues in Drug Development and Bioequivalence (Lisbon 🇵🇹)
25th PAGE meeting (Lisbon 🇵🇹)
To New Shores in Drug Development Implementing Statistical Innovation (Vienna 🇦🇹)
BE Workshop (Moscow 🇷🇺)
2nd Workshop of the Global Bioequivalence Harmonisation Initiative (Rockville 🇺🇸)
BioBridges (Prague 🇨🇪)
- 2017 BioBridges (Prague 🇨🇪)
2nd Annual Biosimilars Forum (Budapest 🇮🇳)
IInd International Conference «Studies of medicinal products: Simple and complex tasks» (Yaroslavl 🇷🇺)
2nd International Symposium on Scientific and Regulatory Advances in Complex Drugs (Budapest 🇮🇳)
- 2018 3rd Workshop of the Global Bioequivalence Harmonisation Initiative (Amsterdam 🇳🇱)
AGAH-Workshop 'Introduction into Basic Principles of Pharmacokinetics' (Oberursel 🇩🇪)
3rd MENA Regulatory Conference on Bioequivalence, Biowaiver, Bioanalysis and Dissolution (Amman 🇮🇪)
BioBridges (Prague 🇨🇪)
3rd Annual Biosimilars Forum (Budapest 🇮🇳)
- 2019 BioBridges (Prague 🇨🇪)
Transforming Data to Insights (Vienna 🇦🇹)
4th Annual Biosimilars Forum (Budapest 🇮🇳)
4th Workshop of the Global Bioequivalence Harmonisation Initiative (Bethesda 🇺🇸)
- 2020 Network of Scientific Excellence (Campinas 🇧🇷)
Some possibly useful thoughts on BE assessments in the case of sparse sampling (Vienna 🇦🇹🇪🇺)

- 2021 Estudos em doses múltiplas para medicamentos genéricos e similares de liberação modificada – Contexto nacional e internacional (São Paulo 🇧🇷🌐)
IIIrd International Conference «The life cycle of medicines: simple and complex tasks» (Yaroslavl 🇷🇺🌐)
- 2022 Bioequivalence. An Old Area with some Uncharted Territories (Vienna 🇦🇹🌐)
Spring School with PKanalix (Paris 🇫🇷🌐)
BioBridges (Prague 🇨🇪)
- 2023 5th Workshop of the Global Bioequivalence Harmonisation Initiative (Amsterdam 🇳🇱)
AGAH-Workshop ‘Introduction into Basic Principles of Pharmacokinetics’ (Oberursel 🇩🇪)
FDA Draft Guidance on Statistical Approaches to Establishing Bioequivalence (FDA SBIA 🇺🇸🌐)
Medicines for Europe: 2nd Bioequivalence Workshop (Brussels 🇧🇪)
Navigating the First ICH Generic Drug Draft Guideline “M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms” (FDA SBIA 🇺🇸🌐)
EUFEPS Open Forum: ICH M13 Bioequivalence Guideline Part A (Frankfurt 🇩🇪)
Bioavailability–Bioequivalence. From Classification to Virtualisation & Anything in Between (Athens 🇬🇷)
BioBridges (Prague 🇨🇪)
AGAH-Workshop ‘Applied Course in Clinical Pharmacokinetics’ (Oberursel 🇩🇪)
25 years SocraTec R&D – Experience meets Expertise (Frankfurt 🇩🇪)
Randomisation versus Random Sampling. Clinical Trials and the Representation Fallacy (Vienna 🇦🇹)
Medicines for Europe: Bioequivalence Working Group meeting (Brussels 🇧🇪)
Translating Nanomedicines from the Lab to the Clinic. Basic Principles for Nanomedicines R&D (Lisbon 🇵🇹🌐)
- 2024 Advanced Pharmacy Practice Research Methods (Lisbon 🇵🇹🌐)
6th Workshop of the Global Bioequivalence Harmonisation Initiative (Rockville 🇺🇸)
SAAMnow Workshop on Data Integrity in BE Studies (Rockville 🇺🇸🌐)
Bridging the Gap between Bayesian & Frequentist Approaches in Clinical Trials for Drug Development (Vienna 🇦🇹)
Advanced Analytical Tools – Multiple Applications for Mass Spectrometry (Lisbon 🇵🇹🌐)
BioBridges (Prague 🇨🇪)
AGAH-Workshop ‘Applied Course in Clinical Pharmacokinetics’ (Oberursel 🇩🇪)
ICH M12 Drug-Drug Interaction Studies Final Guidance (FDA SBIA 🇺🇸🌐)
Molecular Biomarkers and Technologies (Lisbon 🇵🇹🌐)
Estimands: The new bedrock of drug development? (Vienna 🇦🇹)
Implementing M13A Guidance: BE for IR Solid Oral Dosage Forms (FDA SBIA 🇺🇸🌐)
- 2025 IGBA, Medicines for Europe: 3rd Bioequivalence Conference (Amsterdam 🇳🇱)
AGES: News and updates from the CHMP and around the Centralized Procedure (Vienna 🇦🇹🌐)
SAAMnow Workshop on Statistical and Data Analysis Issues and Solutions for ANDAs and 505(b)(2) NDAs (Rockville 🇺🇸🌐)
BioBridges (Prague 🇨🇪)
AGAH Applied Course ‘Introduction into basic principles of clinical pharmacokinetics’ (Oberursel 🇩🇪)
- 2026 Generic Drugs Forum 2026 (FDA SBIA 🇺🇸🌐)
Standard errors in representing Fisher’s views on randomisation (Vienna 🇦🇹)

Workshops / internal trainings

Bioequivalence (Vienna 🇦🇹 1995, 1996, 2011, Aesch 🇨🇭 2008, 2011, Nijmegen 🇳🇱 2010, Ljubljana 🇸🇮 2010, Holzkirchen 🇩🇪 2010, Munich 🇩🇪 2010, Nyon 🇨🇭 2012, Bucharest 🇷🇴 2013, Kaunas 🇱🇹 2017, Novo mesto 🇸🇮 2025)
Regulatory Update and Overview of BE and BA Testing with an Industry Perspective (Istanbul 🇹🇷 2006)
Workshop on Statistics for Bioequivalence Studies (Prague 🇨🇪 2009, Moscow 🇷🇺 2012)
Design and Interpretation of Bioequivalence Studies – Current and Future Issues (Berlin 🇩🇪 2010)
Workshop on Bioanalytics (Prague 🇨🇪 2010)
Workshop on GCP and Logistics for Bioequivalence Studies (Vienna 🇦🇹 2011)
Advanced training on PK, statistics and analytics in Bioequivalence Studies in Russia (Moscow 🇷🇺 2012, 2014)
Seminar on BE Studies (Prague 🇨🇪 2012)
Workshop in Statistics for Bioequivalence (Ulm 🇩🇪 2013, Zagreb 🇭🇷 2013)

Design and Evaluation of Bioequivalence Studies (Barcelona 🇪🇸 2014)
 PK-NCA, PK-based Design, Biostatistics (Prague 🇨🇪 2015)
 Drug Modeling & Consulting (Bilbao 🇪🇸 2016)
 Bioequivalence, Dissolution & IVIVC (Berlin 🇩🇪 2016, Vienna 🇦🇹 2017, León 🇪🇸 2017, Barcelona 🇪🇸 2017, 2018, Athens 🇬🇷 2018)
 Inflation of the Type I Error in Reference-Scaled Average Bioequivalence (Vienna 🇦🇹 2016, Prague 🇨🇪 2016)
 Course on Pharmacokinetics and Bioequivalence (Budapest 🇭🇺 2017)
 Open Issues in the Assessment of Bioequivalence and Biosimilarity (Budapest 🇭🇺 2017)
 Basic Statistical Concepts behind BE Testing (Pamplona 🇪🇸 2018)
 Introduction into Basic Principles of Pharmacokinetics (Oberursel 🇩🇪 2018, 2022 – 2025)
 Sample Size Estimation for Bioequivalence (Amman 🇩🇪 2018)
 Statistical Assessment of Bioequivalence Studies (Gdańsk 🇵🇱 2019)
 Dissolution, Bioequivalence & Biowaivers (Athens 🇬🇷 2019)
 BE Course (Bilbao 🇪🇸 2021)

Posters

Eichinger A, Schütz H, Nitsche V. *Development and Application of an HPLC Determination of Buspirone in Plasma by Solid-Phase Extraction and On-Line Precolumn Trace Enrichment*. International Symposium on Coupled Column Separations (Uppsala 🇸🇪 1988, Oct 26–27). Poster 7.

Eichinger A, Schütz H, Nitsche V. *Anwendung von Säulenschaltungen in der HPC anhand von Beispielen*. 6. Forum Analytik (Vienna 🇦🇹 1989, Jan 23–25).

Eichinger A, Schütz H, Nitsche V. *Spurenanalytik von Arzneistoffen aus biologischen Matrices*. VIII. Wissenschaftliche Tagung der Österreichischen Pharmazeutischen Gesellschaft (Graz 🇦🇹 1989, Oct 26–28).

Eichinger A, Schütz H, Nitsche V. *Determination of Buspirone in Plasma by HPLC with Solid-Phase Extraction and On-Line Precolumn Trace Enrichment and its Application to a Pharmacokinetic Study*. 4th European Congress of Biopharmaceutics and Pharmacokinetics (Geneva 🇨🇭 1990, Apr 17–19). *Europ J Drug Metabol Pharmacokin*. 1990; 15(1): P234.

Schütz H, Eichinger A, Nitsche V. *Determination of Amoxicillin and Ampicillin using a new HPLC Method with Post-Column Derivatization and its Application to Bioavailability Studies*. 4th European Congress of Biopharmaceutics and Pharmacokinetics (Geneva 🇨🇭 1990, Apr 17–19). *Europ J Drug Metabol Pharmacokin*. 1990; 15(1): P235.

Schütz H, Eichinger A, Krenauer J, Kaspar A, Wolf C, Nitsche V. *Implementierung der GLP in einem Auftragsforschungslabor mit 6 Mitarbeitern*. 10. Forum Analytik (Vienna 🇦🇹 1993, Jan 25–27).

Henry A, Schütz H, Hughes L, Davis S. *Performing Reference-Scaled Average Bioequivalence (RSABE) in Phoenix[®] WinNonlin[®]*. AAPS Annual Meeting and Exposition (San Antonio 🇺🇸 2013, Nov 10–14). Poster T2350. doi:10.13140/RG.2.1.1008.0800.

König F, Wolfsegger MJ, Jaki T, Schütz H, Wassmer G. *Adaptive two-stage bioequivalence trials with early stopping and sample size re-estimation*. 35th Annual Conference of the International Society for Clinical Biostatistics (Vienna 🇦🇹 2014, Aug 24–28). Poster P1.2.88. doi:10.13140/RG.2.1.5190.0967.

König F, Wolfsegger MJ, Jaki T, Schütz H, Wassmer G. *Adaptive two-stage bioequivalence trials with early stopping and sample size re-estimation*. 3rd International Clinical Trials Methodology Conference (Glasgow 🇬🇧 2015, Nov 16–17) Poster 218. *Trials* 16(Suppl 2): P218. doi:10.1186/1745-6215-16-S2-P218.

Booth J, Schütz H, Steinitz-Trost K, Lee H-Y, Bauer A, Wolfsegger M. *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*. XXVI Congress of the International Society on Thrombosis and Haemostasis and 63rd Annual Scientific and Standardization Committee Meeting (Berlin 🇩🇪 2017, Jul 8–13) PB 1131.

Booth J, Schütz H, Steinitz-Trost K, Lee H-Y, Bauer A, Wolfsegger M. *Minimum half-life extension ratio model for reduced dosing frequency of extended half-life recombinant FVIII products*. HAA Annual Scientific Meeting (Sydney 🇦🇺 2017, Oct 29–Nov 01). P223.

Mehl C, Henry A, Hughes L, Schütz H. *Reference-Scaled Average Bioequivalence (RSABE) Approach For Compounds With A Narrow Therapeutic Index (NTID) Using Phoenix[™] WinNonlin[®]*. AAPS Annual Meeting and Exposition (San Diego 🇺🇸 2017, Nov 12–16). Poster W2087. doi:10.13140/RG.2.2.35361.30564.

Booth J, Schütz H, Steinitz-Trost K, Lee H-Y, Bauer A, Wolfsegger M. *A Model of the Minimum Half-life Extension Ratio Needed to Reduce the Dosing Frequency of Extended Half-life (EHL) Recombinant FVIII (rFVIII) Products*. 62nd Annual Meeting of the Society of Thrombosis and Haemostasis Research (Vienna 🇦🇹 2018, Feb 20–23). P160.

Ring A, Lang B, Kazaroho C, Labes D, Awounvo JS, Schütz H. *Assurance (expected power) for planning crossover bioequivalence trials*. *Pharmacology* 2018 (London 🇬🇧, 2018, Dec 18–20). P79. *Br J Clin Pharmacol*. 2019; 85: 1622. doi:10.1111/bcp.13937.

Publications

- 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. PMID 6698663.
- Mascher H, Nitsche V, Schütz H. *Separation, Isolation and Identification of Optical Isomers of 1,4-Benzodiazepine Glucuronides from Biological Fluids by Reversed-Phase High-Performance Liquid Chromatography*. J Chromatogr Biomed Appl. 1984; 306: 231–9. doi:10.1016/S0378-4347(00)80885-3.
- Nitsche V, Mascher H, Schütz H. *Bioverfügbarkeit von Amilorid-Hydrochlorothiazid-Kombinationspräparaten*. Therapiewoche. 1985; 36(1): 56–60.
- 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. doi:10.1016/0378-4347(87)80175-5.
- Nitsche V, Lauschner R, Eichinger A, Schütz H. *Absolute Bioverfügbarkeit von Ambroxol-Zäpfchen*. Pharm Ztg. 1988; 133(32): 28–33.
- 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. PMID 9089000.
- 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. PMID 9089001.
- Schütz H. *An extremely strange observation?* [letter]. Eur J Drug Metabol Pharmacokinet. 2004; 29(1): 69–71. doi:10.1007/BF03190576.
- 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. doi:10.5414/cpp44135.
- 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. doi:10.5414/cpp47761.
- Leis HJ, Schütz H, Windischhofer W. *Quantitative determination of methylphenidate in plasma by gas chromatography negative ion chemical ionisation mass spectrometry using o-(pentafluorobenzoyloxycarbonyl)-benzoyl derivatives*. Anal Bioanal Chem. 2011; 400(8): 2663–70. doi:10.1007/s00216-011-5048-6.
- Schütz H, Labes D, Fuglsang A. *Reference Datasets for 2-Treatment, 2-Sequence, 2-Period Bioequivalence Studies*. AAPS J. 2014; 16(6): 1292–7. doi:10.1208/s12248-014-9661-0. PMID 4389751.
- 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. doi:10.1208/s12248-014-9680-x. PMID 4287291.
- Schütz H. *Two-stage designs in bioequivalence trials*. Eur J Clin Pharmacol. 2015; 71(3): 271–81. doi:10.1007/s00228-015-1806-2.
- Fuglsang A, Schütz H, Labes D. *Reference Datasets for Bioequivalence Trials in a Two-Group Parallel Design*. AAPS J. 2015; 17(2): 400–4. doi:10.1208/s12248-014-9704-6. PMID 4365103.
- 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. doi:10.1007/s11095-016-2006-1.
- 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. doi:10.1208/s12248-017-0063-y.
- 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. doi:10.1111/hae.13483.
- 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. doi:10.1111/bcp.14055. PMID 6783617.
- 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. doi:10.1208/s12248-020-0427-6.
- 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 2x2 crossover designs*. Biom J. 2021; 63(1): 122–33. doi:10.1002/bimj.201900388.
-  Pearls of Bioequivalence Award 2022 by ‘The Frankfurt Foundation Quality of Medicines’ and the EUFEPS ‘Network Bioavailability and Biopharmaceutics’.
- 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. doi:10.1002/pst.2074.

Schütz H, Labes D, Wolfsegger MJ. *Critical Remarks on Reference-Scaled Average Bioequivalence*. J Pharm Pharmaceut Sci. 2022; 25: 285–96. doi:10.18433/jpps32892.

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. doi:10.2478/sjcapp-2023-0014.

Schütz H, Burger DA, Cobo E, Dubins D, Farkas 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. doi:10.1208/s12248-024-00921-x.

Schütz H, Burger DA, Cobo E, Dubins D, Farkas 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. doi:10.1208/s12248-024-01008-3.

Osuchowski MF, Adamik H, Gozdzik W, Mascher D, Redl H, Winkler MS, Schütz H, Mascher H. *The novel biomarker t⁶A accurately identified septic patients at admission but failed to predict outcome*. Critical Care. 2025; 29:129. doi:10.1186/s13054-025-05354-2.

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. doi:10.1002/pst.70088.

Schütz H. (2026). *Sex-by-Treatment Interaction in Comparative Bioavailability Studies*. Manuscript in preparation.

Packages

Schütz H. *AdaptiveBE: Acceptability of Adaptive Bioequivalence Studies*. 2018; Package version 0.8.4.9000. <https://github.com/Helmut01/AdaptiveBE>.

Molins E, Labes D, Schütz H, Ocaña J. *betsd: Adjusting significance levels in two-stage adaptive 2x2 crossover designs*. 2019; Package version 0.1.5. <https://github.com/eduard-molins/betsd>.

Schütz H. *indirectBE: Adjusted Indirect Comparisons*. 2021; Package version 0.3.0.

Labes D, Lang B, Schütz H. *Power2Stage: Power and Sample-Size Distribution of 2-Stage Bioequivalence Studies*. 2021; Package version 0.5-4. doi:10.32614/CRAN.package.Power2Stage.

Schütz H, Tomashevskiy M, Labes D. *replicateBE: Average Bioequivalence with Expanding Limits (ABEL)*. 2022; Package version 1.1.3. doi:10.32614/CRAN.package.replicateBE.

Labes D, Schütz H, Lang B. *PowerTOST: Power and Sample Size Based on Two One-Sided t-Tests (TOST) for (Bio) Equivalence Studies*. 2025; Package version 1.5-7. doi:10.32614/CRAN.package.PowerTOST.

IT-Proficiency

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

Certifications

1980 +	Diver *	CMAS
1981 +	Open Water Scuba Diver	PADI
1993 +	Advanced Open Water Diver, Rescue Diver	PADI
1995	Divemaster	PADI
1995 – 2005	Open Water Scuba Instructor	PADI
1997 +	Cavern Diver, Introduction to Cave Diving, Cave Diver	NACD
2002 +	Nitrox User Level I + II	NRC

