



## Ing. Helmut Schütz

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[helmut.schuetz@meduniwien.ac.at](mailto:helmut.schuetz@meduniwien.ac.at)

### Personal Details

Nationality: Austrian  
 Age: 65

### Education

1974 – 1979

#### Secondary College for Chemical Engineering

*Vienna*

Educational focus: Technical Chemistry, final examination passed with distinction.  
 Standesbezeichnung „Ingenieur“ (Professional Designation ‘Engineer’).

1983

### Language Skills

Native German, fluent in spoken and written English. Τραυλίζει στα ελληνικά.

### Activities

1980

#### Gerot Pharmazeutika GesmbH

*Vienna*

Syntheses of NCEs (beta blockers, benzodiazepines).

1980 – 1984

#### Pharmakologische Untersuchungsgesellschaft mbH

*Vienna*

Trace analysis (GC/HPLC).  
 Development of software, evaluation of Phase I studies.

1984 – 2004

#### Biokinet GmbH

*Vienna*

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

*Vienna*

Independent Consultant in the domain of bioavailability and bioequivalence studies.  
 Biostatistical services (design, evaluation, and assessment of studies; lectures, workshops).  
 Support at regulatory meetings.

2016 – current

Maintainer of the Bioequivalence and Bioavailability Forum.

2022 – current

#### Institute of Medical Statistics, 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&amp;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 <sup>rd</sup> 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 <sup>th</sup> 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 <sup>th</sup> European Congress of Biopharmaceutics and Pharmacokinetics (Brussels 🇧🇪) HPLC Seminar for Professionals (Korneuburg 🇦🇹) 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 🇦🇹)

- 1995 BIOKINET 95: Criteria of Bioequivalence (Vienna   
2<sup>nd</sup> EUFEPS Nuremberg Conference: Symposium on Quality and Interchangeability of Topical Products for Local Action (Nuremberg 
- 1996 BIOKINET 96: Current Developments in the Testing of Topical Medicinal Products with Local Effect (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   
2<sup>nd</sup> 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   
3<sup>rd</sup> CMD(h)-EGA Symposium on Bioequivalence (London   
2<sup>nd</sup> 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   
2<sup>nd</sup> 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   
3<sup>rd</sup> International Regulatory Workshop on Bioequivalence, Bioanalysis, Dissolution and Biosimilarity (Budapest 
- 2013 Advanced concepts of IVIVC through case studies; Biostatistical aspects of Reference-scaled & Two stage designs (Mumbai 








- 2013 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 )  
 1<sup>st</sup> MENA Regulatory Conference on Bioequivalence, Biowaiver, Bioanalysis and Dissolution (Amman )  
 5<sup>th</sup> 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 Biosimilarity (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<sup>®</sup> for WinNonlin<sup>®</sup> Version 6.2.x & 6.3 (Munich )  
 Bioequivalence Studies in Russia: Pharmacokinetics, Statistics and Analytics (Moscow )  
 Bioavailability / Bioequivalence, Dissolution and Biowaivers (Budapest )  
 4<sup>th</sup> 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 Hämophilie A (Munich )  
 EUFEPS BABP Network: 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 )  
 5<sup>th</sup> Scientific Conference «Clinical Trials of Medicines in Ukraine» (Kyiv )
- 2016 Scientific and Regulatory Issues in Drug Development and Bioequivalence (Lisbon )  
 25<sup>th</sup> PAGE meeting (Lisbon )  
 To New Shores in Drug Development Implementing Statistical Innovation (Vienna )  
 BE Workshop (Moscow )  
 EUFEPS BABP Network: Global Bioequivalence Harmonisation Initiative (Rockville )  
 BioBridges (Prague )
- 2017 BioBridges (Prague )  
 2<sup>nd</sup> Annual Biosimilars Forum (Budapest )  
 II<sup>nd</sup> International Conference «Studies of medicinal products: Simple and complex tasks» (Yaroslavl )  
 2<sup>nd</sup> International Symposium on Scientific and Regulatory Advances in Complex Drugs (Budapest )
- 2018 EUFEPS BABP Network: Global Bioequivalence Harmonisation Initiative (Amsterdam )  
 AGAH-Workshop “Introduction into Basic Principles of Pharmacokinetics” (Oberursel )  
 3<sup>rd</sup> MENA Regulatory Conference on Bioequivalence, Biowaiver, Bioanalysis and Dissolution (Amman )  
 BioBridges (Prague )  
 3<sup>rd</sup> Annual Biosimilars Forum (Budapest )
- 2019 BioBridges (Prague )  
 Transforming Data to Insights (Vienna )  
 4<sup>th</sup> Annual Biosimilars Forum (Budapest )  
 EUFEPS BABP Network: 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 )  
 III<sup>rd</sup> International Conference «The life cycle of medicines: simple and complex tasks» (Yaroslavl )  
 Bioequivalence. An Old Area with some Uncharted Territories (Vienna )
- 2022 Spring School with PKanalix (Paris )  
 BioBridges (Prague )








- 2022 EUFEPS BABP Network: Global Bioequivalence Harmonisation Initiative (Amsterdam )  
AGAH-Workshop “Introduction into Basic Principles of Pharmacokinetics” (Oberursel )
- 2023 FDA Draft Guidance on Statistical Approaches to Establishing Bioequivalence  
(FDA SBIA Webinar )  
Medicines for Europe: 2<sup>nd</sup> Bioequivalence Workshop (Brussels )  
Navigating the First ICH Generic Drug Draft Guideline “M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms” (FDA SBIA Webinar )  
EUFEPS Open Forum: ICH M13 Bioequivalence Guideline Part A (Frankfurt )  
Bioavailability–Bioequivalence. From Classification to Virtualisation & Anything in Between (Athens )

## Workshops / internal trainings

- Regulatory Update and Overview of BE and BA Testing with an Industry Perspective (Istanbul ) 2006)
- Bioequivalence (Aesch ) 2008, 2011, Nijmegen ) 2010, Ljubljana ) 2010, Munich ) 2010, Holzkirchen ) 2010, Vienna ) 2011, Nyon ) 2012, Bucharest ) 2013, Kaunas ) 2017)
- 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 pharmacokinetics, 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, Barcelona ) 2017, Vienna ) 2017, León ) 2017, Barcelona ) 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)
- 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*. 4<sup>th</sup> 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*. 4<sup>th</sup> 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<sup>®</sup> WinNonlin<sup>®</sup>*. 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*. 35<sup>th</sup> 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*. 3<sup>rd</sup> 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 63<sup>rd</sup> 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*. 62<sup>nd</sup> 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-(pentafluorobenzoyloxy)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. [PMC](#) 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. [PMC](#) 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.

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## 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 (CreoSoft), WinSAAM (WinSAAM Inc), Boomer (Bourne), Kinetica (Thermo Scientific), Berkley Madonna (Macey & Oster), EquipTest/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 (MS), 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 – 1996	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)

