



## Helmut Schütz, BEng

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### Personal Details

Nationality: Austrian  
 Age: 60  
 Place of Birth: Vienna

### Education

1974 – 1979

#### Secondary College for Chemical Engineering

*Vienna*

Educational Focus: Technical Chemistry, Final Examination passed with Distinction.  
 Degree 'Ingenieur' (Chemical Engineer).

1983

### Language Skills

Native German, fluent in spoken and written English.

### Activities

1980 – 1981

#### Gerot Pharmazeutika GesmbH

*Vienna*

Syntheses of NCEs ( $\beta$ -blockers, benzodiazepines).

1981 – 1984

#### Pharmakologische Untersuchungsgesellschaft mbH

*Vienna*

Trace Analysis (GC/HPLC).

Development of Software, Evaluation of Bioequivalence and Pharmacokinetic Studies.

1984 – 2004

#### Biokinet GmbH

*Vienna*

Manager of the Analytical Laboratory.

Development and Validation of Analytical Methods for the Determination of Drugs in Biological Matrices.

1984 – 1987

Manager of the Department of Biostatistics and Data Management.

Design, Implementation, Administration of a Laboratory Information Management System (LIMS) according to the Rules of GLP (Good Laboratory Practices).

Design and Evaluation of more than 500 Phase I Studies.

Assessment of about 50 Phase I Studies of external Contract Research Organizations (CROs).

1987 – 2004

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).

Contractor Selection and Supervision, Support at Regulatory Meetings.

Administrator of the BEBA Internet Forum.

### 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

2010 +

FIP International Pharmaceutical Federation

2014 +  
2015 +  
2018 +  
  
2015 +

AAPS American Association of Pharmaceutical Scientists  
 EUFEPS European Federation for Pharmaceutical Sciences  
 AGAH Arbeitsgemeinschaft für Angewandte Humanpharmakologie (Association for Applied Human Pharmacology)  
 Editorial Board of *Drugs in R&D*.

## IT-Proficiency

Operating Systems: UNIX-HP/UX [Hewlett Packard], DOS [M\$], M\$-Windows [XP/Vista/Win7]  
 Networks: LanManager [HP, M\$], Samba [GNU]  
 GUIs: CDE [HP], M\$-Windows [v3.11/NT4/2000]  
 Scripts/Macros: Awk, C-Shell [Unix], BAT, Access, Excel [M\$], JavaScript [Sun]  
 Languages: BASIC-Dialects (Rocky Mountain Basic [HP], HTB [TransEra], GWBasic/QuickBasic/VBA [M\$], CRA-Basic [Shimadzu]), Pascal for Workstations [HP], TurboPascal [Borland]  
 Web: (X)HTML, CSS, Apache [GNU], PHP [GNU]  
 Databases: dBase [Ashton-Tate], ACCESS [M\$], MySQL [Oracle]  
 LIMS: LAB/UX [HP/Agilent Technologies]  
 Software: BioEvaluat (Biokinet), Statistica (StatSoft), StatXact (Cyxel), Phoenix|WinNonlin/NLME (Certara Pharsight), EquivTest/PK (Statistical Solutions), MONOLIX (The Monolix Group), NCSS (NCSS Software), StudySize/Result (CreoSoft), TOPFIT (Springer), Kinetica (Thermo Scientific), WinBUGS / PKBugs (GNU), Berkley Madonna (Macey & Oster), BIOEQV (Wijnand), Boomer (Bourne), WinSAAM (WinSAAM Inc), R (The R Foundation for Statistical Computing), Acrobat (Adobe), Office (M\$, Apache), ...

## Presentations / Continuing Education

Derivatization in GC (🇦🇹 Vienna 1982)  
 Bioavailability/Bioequivalence, Pharmaceutical and Therapeutic Equivalence (🇩🇪 Würzburg 1987)  
 European Congress of Biopharmaceutics and Pharmacokinetics (🇩🇪 Freiburg 1987, 🇨🇭 Geneva 1990, 🇧🇪 Brussels 1993)  
 Forum Analytik (🇦🇹 Vienna 1988, 1989, 1991, 1992, 1993)  
 International Symposium on Coupled Column Separation (🇸🇪 Uppsala 1988)  
 Background – Design – Analysis & Interpretation of Bioavailability / Bioequivalence Studies (🇬🇧 London 1990)  
 Bioavailability and Pharmacokinetics (🇳🇱 Amsterdam 1990)  
 Modern Methods for Drug Monitoring and their Impact on Clinical Practice (🇦🇹 Graz 1990)  
 Analytical Methods Validation: Bioavailability, Bioequivalence and Pharmacokinetic Studies Conference (🇺🇸 Arlington 1990)  
 Workshop in Pharmacokinetic Modeling (🇺🇸 Palo Alto 1991)  
 Workshop in Bioavailability/Bioequivalence (🇺🇸 Palo Alto 1991)  
 LIMS Workshop (🇦🇹 Linz 1992)  
 International Open Conference on Dissolution, Bioavailability, Bioequivalence (🇨🇦 Toronto 1992)  
 Oral Modified-Release Dosage Forms: Biopharmaceutical Challenges and Clinical Implications (🇸🇪 Stockholm 1992)  
 Computerized Data Handling – Current Trends in Pharmaceutical and Clinical Research (🇩🇪 Neu-Ulm 1993)  
 Bio-International Conference (🇩🇪 Munich 1994, 🇬🇧 London 1999, 2003, 2005, 2008)  
 Dissolution Testing, Bioequivalence & Bioavailability Studies (🇧🇪 Brussels 2004)  
 Dissolution, Bioavailability & Bioequivalence (🇳🇱 Amsterdam 2005)  
 Dissolution Testing, Bioavailability & Bioequivalence (🇭🇺 Budapest 2006, 2007, 🇩🇪 Berlin 2007)  
 International Regulatory Workshop on Bioequivalence and Dissolution (🇭🇺 Budapest 2006)  
 EGA Workshop on Bioequivalence Study Design, Working to GCP and Interpreting the Guidelines (🇵🇹 Lisbon 2007)  
 Dissolution, Bioavailability and Bioequivalence (🇭🇺 Budapest 2008, 🇨🇪 Prague 2008)  
 Dissolution Testing, Bioequivalence and Bioavailability Strategies (🇬🇧 London 2008)  
 Increasing Predictability in Gastrointestinal Simulation (🇳🇱 Zeist 2008)  
 Second World Conference on Magic Bullets – Ehrlich II (🇩🇪 Nuremberg 2008)  
 CMD(h)-EGA Symposia on Bioequivalence (🇫🇷 Paris 2008, 🇬🇧 London 2010)  
 Bioavailability, Bioequivalence, Pharmacokinetics & Beyond (🇮🇳 Ahmedabad 2008)  
 EUFEPS BABP Open Discussion Forum (🇩🇪 Bonn 2009, 🇪🇸 Barcelona 2011)  
 Bioequivalence and Bioavailability (🇭🇺 Budapest 2009, 🇸🇮 Ljubljana 2010)  
 Introduction to Phoenix WinNonlin 6.0 (🇩🇪 Munich 2009)  
 EBF & EUFEPS Workshop: EMEA Draft Guideline on Validation of Bioanalytical Methods (🇧🇪 Brussels 2010)  
 International Regulatory Workshops on Bioequivalence, Bioanalysis, Dissolution and Biosimilarity (🇭🇺 Budapest 2010, 2012, 2014)  
 Bioequivalence and Bioavailability Studies (🇩🇪 Munich 2010, 🇧🇪 Brussels 2011)

Biostatistics: Basic concepts & applicable principles for various designs in bioequivalence studies and data analysis (🇮🇳 Mumbai 2011)  
 Bioavailability/Bioequivalence and Dissolution Testing (🇮🇪 Budapest 2011)  
 International Symposium on BA/BE of Oral Drug Products (🇯🇵 Kobe 2011)  
 Innovations in Modified Release (🇩🇪 Berlin 2011)  
*In vitro in vivo* Correlation (IVIVC), Biowaivers & Statistical Aspects of Bioequivalence in Drug Product Development (🇮🇳 Mumbai 2012)  
 Drug development and registration «Pharma-2020» Implementation Strategy (🇷🇺 Moscow 2012)  
 Advanced concepts of IVIVC through case studies; Biostatistical aspects of Reference-scaled & Two stage designs (🇮🇳 Mumbai 2013)  
 Bioavailability / Bioequivalence, Dissolution and Biowaivers (🇮🇪 Budapest 2013, 2014, 🇨🇪 Prague 2015)  
 EUFEPS BABP Open Discussion Forum on the Revised European Guideline on Pharmacokinetic and Clinical Evaluation of Modified Release Dosage Forms (🇩🇪 Bonn 2013)  
 Bioequivalence Assessment of Oral Dosage Forms (🇧🇪 Leuven 2013)  
 MENA Regulatory Conference on Bioequivalence, Biowaiver, Bioanalysis and Dissolution (🇸🇦 Amman 2013, 2018)  
 5<sup>th</sup> BBBB International Conference. From Drug Discovery and Formulation Strategies to Pharmacokinetics and Pharmacodynamics (🇬🇷 Athens 2013)  
 Clinical Development Workshop (🇨🇪 Prague 2013)  
 Haemophilia Master Class: Personalized Treatment and Care (🇩🇪 Munich 2014, 🇩🇪 Frankfurt 2014)  
 Innovative Statistical Approaches in Drug Development (🇦🇹 Vienna 2014)  
 Spanish Congress of Pharmacy and Pharmaceutical Technology (🇪🇸 Barcelona 2015)  
 Interaktiver Workshop PK-Dosing in der Hämophilie A (🇩🇪 Munich 2015)  
 EUFEPS BABP Network: Global Bioequivalence Harmonisation Initiative (🇳🇱 Amsterdam 2015, 🇺🇸 Rockville 2016, 🇳🇱 Amsterdam 2018)  
 EMA / EGA joint workshop on the impact of the revised EMA Guideline on the Pharmacokinetic and Clinical Evaluation of Modified Release Dosage Form (🇬🇧 London 2015)  
 International Symposium on Scientific and Regulatory Advances in Complex Drugs (🇮🇪 Budapest 2015, 2016)  
 5<sup>th</sup> Scientific Conference “Clinical Trials of Medicines in Ukraine” (🇺🇦 Kiev 2015)  
 Scientific and Regulatory Issues in Drug Development and Bioequivalence (🇵🇹 Lisbon 2016)  
 25<sup>th</sup> PAGE meeting (🇵🇹 Lisbon 2016)  
 To New Shores in Drug Development Implementing Statistical Innovation (🇦🇹 Vienna 2016)  
 BA/BE Workshop (🇨🇪 Prague 2016)  
 BE Workshop (🇷🇺 Moscow 2016)  
 BioBridges (🇨🇪 Prague 2017, 2018)  
 Annual Biosimilars Forum (🇮🇪 Budapest 2017, 2018)  
 II<sup>nd</sup> International Conference «Studies of medicinal products: Simple and complex tasks» (🇷🇺 Yaroslavl 2017)

## Workshops / in-house 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)  
 Advanced training on pharmacokinetics, statistics and analytics in Bioequivalence Studies in Russia (🇷🇺 Moscow 2012, 2014)  
 Seminar on BE Studies (🇨🇪 Prague 2012)  
 Workshop in Biostatistics 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)

## 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, Sweden; 1988, October 26–27: Poster 7.
- 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, Switzerland; 1990, April 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, Switzerland; 1990, April 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, Austria; 1993, January 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, TX; 2013, November 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, Austria; 2014, August 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, UK; 2015, November 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 (SSC) Meeting, Berlin, Germany; 2017, July 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, Australia; 2017, October 29–November 01: P223.
- Mehl C, Henry A, Hughes L, Schütz H. *Reference-Scaled Average Bioequivalence (RSABE) Approach For Compounds With A Narrow Therapeutic Index (NTI) Using Phoenix<sup>™</sup> WinNonlin<sup>®</sup>*. AAPS Annual Meeting and Exposition, San Diego, CA; 2017, November 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, Austria; 2018, February 20–23: P160.

## Papers

- Nitsche V, Mascher H, Schütz H. *Comparative bioavailability of several phenytoin preparations marketed in Austria*. *Int J Clin Pharm 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 Pharm 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 Pharm Ther*. 1997;35(3):117–22. PMID 9089001.
- Schütz H. *An extremely strange observation?* [letter]. *Europ J Drug Metabol Pharmacokin*. 2004;29(1):69–71. PMID 15151173.

- 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 Pharm Ther. 2006;44(3):135–41. doi:10.5414/PPP44135.
- 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 Pharm Ther. 2009;47(12):761–9. doi:10.5414/PPP47761.
- Leis HJ, Schütz H, Windischhofer W. *Quantitative determination of methylphenidate in plasma by gas chromatography negative ion chemical ionisation mass spectrometry using o-(pentafluorobenzyloxy-carbonyl)-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. [free resource](#).
- 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. [free resource](#).
- Schütz H. *Two-stage designs in bioequivalence trials*. Eur J Clin Pharm. 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. [free resource](#).
- 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, Schütz H. *Sample size determination in bioequivalence studies using assurance instead of power*. In preparation 2019.
- Wolfsegger JM, Bauer A, Labes D, Schütz H, Vonk R, Hale MD. *A Note on Assessment of Dose-Proportionality*. In preparation 2019.
- 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*. In preparation 2019.
- Schütz H. *Group-Effects in Bioequivalence Studies*. In preparation 2019.

## R packages

- Labes D, Schütz H, Lang B. *PowerTOST: Power and Sample Size Based on Two One-Sided t-Tests (TOST) for (Bio)Equivalence Studies*. 2018; R package version 1.4-7.
- Labes D, Lang B, Schütz H. *Power2Stage: Power and Sample-Size Distribution of 2-Stage Bioequivalence Studies*. 2018; R package version 0.5-1.
- Schütz H, Tomashevskiy M, Labes D. *replicateBE: Average Bioequivalence with Expanding Limits (ABEL)*. 2017; R package version 1.0-5.9000.
- Schütz H. *AdaptiveBE: Acceptability of Adaptive Bioequivalence Studies*. 2017; R package version 0.8-3.9000.