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.

1983 Degree ‘Ingenieur’ (Chemical Engineer).

Language Skills

Native German, fluent in spoken and written English.

Activities

1980 – 1981 **Gerot Pharmazeutika GesmbH**
Vienna
Syntheses of NCEs (β-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

1984 – 1987 Manager of the Analytical Laboratory.
Development and Validation of Analytical 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 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).

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 BE/BA 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 +
2015 +

AAPS American Association of Pharmaceutical Scientists
EUFEPS European Federation for Pharmaceutical Sciences
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)
Biovailability and Pharmacokinetics (Amsterdam 1990)
Modern Methods for Drug Monitoring and their Impact on Clinical Practice (Graz 1990)
Analytical Methods Validation: Biovailability, 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)
5th BBBB International Conference. From Drug Discovery and Formulation Strategies to Pharmaco-kinetics 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, 2018)
5th Scientific Conference “Clinical Trials of Medicines in Ukraine” (Kiev 2015)
Scientific and Regulatory Issues in Drug Development and Bioequivalence (Lisbon 2016)
25th 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)
IInd 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)
Bioequivalence (Kaunas 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.* 4th 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.* 4th 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, 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® WinNonlin®.* 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.* 35th 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.* 3rd 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 63rd 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 (NTID) Using Phoenix™ WinNonlin®.* 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.* 62nd 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 Isomeres of 1,4-Benzodiazepine Glucuronides from Biological Fluids by Reversed-Phase High-Performance Liquid Chromatography.* J Chromatogr, Biomed Appl. 1984;306:231–9. PMID 6715462.

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

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. PMID 3667823.

Nitsche V, Lauschner R, Eichinger A, Schütz H. *Absolute Bioverfügbarkeit von Ambroxol-Zäpfchen.* Pharm Ztg. 1988;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/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 Pharm 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-(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.

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.

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 2-Group Parallel Design.* AAPS J. 2015;17(2):400–4. doi:10.1208/s12248-014-9704-6.

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.

Schütz H, Tomashevskiy M, Labes D, Shitova A, González-de la Parra M. *Reference Datasets for Studies in a Replicate Design intended for Average Bioequivalence with Expanding Limits.* In preparation 2018.

Schütz H. *Group-Effects in Bioequivalence Studies.* In preparation 2018.

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.