

## DR. NORBERT HANDLER, MBA

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### PERSONAL BACKGROUND

- Nationality Austria
- Date/place of birth March, 17<sup>th</sup> 1974, Neunkirchen/Austria

### PROFILE

- Registered "Consulting Engineer for Pharmacy" in Austria
- General Authorized and Certified Expert for pharmaceutical chemistry at the Trade Court Vienna
- Several years of experience in pharmaceutical academic and industrial R&D
- Strong written and verbal communication and presentation skills
- Strong interdisciplinary and analytical skills; highly target oriented

### PROFESSIONAL EXPERIENCE

- Since 03/2014 **Co-founder and Managing Partner**  
RD&C Research, Development & Consulting GmbH; Vienna/Austria
  - Project management
  - IMPD, CMC, CTD module 3 (gap analysis, documentation, writing)
  - Regulatory advice (CMC and quality documentation)
  - Medicinal chemistry
  - Evaluation of pharmaceutical processes (quality issues)
  - Impurity profiling, degradation products
  - Stability of drug substances and products
  - Environmental Risk Assessment
  - Expert Reports, QOS
  - Analytics
- 10/2011 – 01/2014 **Head Drug Discovery & Development**  
Savira pharmaceuticals GmbH; Vienna/Austria
  - Molecular Modeling: design and modeling of relevant structures; evaluation and ranking of results
  - Medicinal Chemistry: communication and feed-back with CROs; molecule selection; design, planning and coordination of chemical synthesis; evaluation of compound properties
  - Compound logistics and management: evaluation of compound stability and storage conditions
  - Analytics: evaluation and assessment of analytical data (NMR, MS, HPLC, GC, IR, etc.); compound stability testing; quality assurance of compounds
  - (Pre-)Formulation: design and evaluation of suitable (pre-)formulations
  - Project Management: scientific management of European project "Flupharm"; coordination of relevant multisite project partners; management and coordination of scientific activities
  - IP Management: evaluation and monitoring of IP space; interface to patent attorneys; preparation and administration of patent applications

- 04/2010 – 10/2011      **Technology transfer manager**  
University of Vienna, Vienna/Austria
  - Management and administration of university's patent portfolio; evaluation and coordination of new patent applications
  - Technology transfer; contract management and negotiations with industrial partners
  - Initiation and coordination of industrial projects and partners; guidance and monitoring of interdisciplinary project applications;
  - Support of potential spin-off founders
  
- 07/2008 – 06/2009      **Erwin Schrödinger Grant (post-doc)**  
ETH Zurich; Zurich/Switzerland
  - Radiopharmaceutical sciences: evaluation of potential PET-Targets; design, planning and execution of cold and hot chemical synthesis; cold and hot analytical methods; <sup>18</sup>F labeling; biological evaluation (assay testing with [<sup>3</sup>H] labeled compounds)
  
- 07/2004 – 05/2010      **University assistant (post-doc)**  
University of Vienna; Vienna/Austria
  - Medicinal chemistry: analytics; evaluation of scientific literature; design, planning, coordination and execution of chemical synthesis; scientific writing; supervision of diploma and PhD students
  - Teaching: Laboratory "Drug Analytics" at University of Vienna and FH Vienna "Biotechnology"

#### EDUCATION

- 10/2010 – 12/2012      MBA General Management  
WWEDU World Wide Education, Wels/Austria
  
- 06/2000 – 11/2003      Doctoral Thesis; PhD  
Department of Medicinal Chemistry, University of Vienna/Austria
  
- 10/1997 – 03/1998      Diploma thesis; Mag. pharm.  
Department of Medicinal Chemistry, University of Vienna/Austria
  
- 10/1992 – 10/1998      Studies Pharmacy  
University of Vienna/Austria
  
- 09/1984 – 06/1992      Secondary School and Matura  
BG und BRG Neunkirchen/Austria

#### FURTHER TRAINING

- ECA Seminar: "GMP-Auditor" (Dec. 2017)

#### SPECIAL SKILLS

- Languages: fluent in German (mother tongue), fluent in English, conversant in French
- Computer skills: Microsoft Office™, ChemDraw™, PyMol™, LigandScout™, EPISuite™, OECD QSAR Toolbox

#### FURTHER ACTIVITIES

- Lecturer Concept Heidelberg: Workshop "Stability-by-design" (ongoing)
- Lecturer University of Vienna: laboratory course "drug analytics" (ongoing)

## CURRENT AND FINISHED PROJECTS

- Regulatory Advice: CMC, quality, drug development process
  - FDA compliance of European CMC documentation (including DMF)
  - Evaluation and gap analysis of CMC documentation
  - Development projects: small molecule, small molecules from biologic sources, biologics
  - Drug development projects at WHO, FDA and EMA
  - Handling and answering of deficiency letters
  - Evaluation of drug development programs
- Writing and evaluation of IMPDs, DMF and module 3 (quality and CMC)
  - ASMF small molecules
  - Antibacterial ointment
  - iv drugs
- Due diligence: CMC part
  - small molecules
  - derivatized peptides
  - biologics
- Profiling and documentation of impurities and degradation pathways and products
- Stability of drug substances and products
- IP strategies
- Expert statements on
  - quality of APIs
  - environmental risks
  - stability and degradation
  - *in silico* mutagenicity assessment

## SCIENTIFIC PUBLICATIONS (Selection)

- Wolkerstorfer A., Buschmann H., Handler N. Scientific and regulatory aspects of solid phase reactions in forced degradation studies. Part 1. Pharm. Ind. 77 (2015) 1484-1491.
- Wolkerstorfer A., Buschmann H., Handler N. Scientific and regulatory aspects of solid phase reactions in forced degradation studies. Part 2. Pharm. Ind. 77 (2015) 1731-1737.
- Wolkerstorfer A., Handler N., Buschmann H. New approaches to treating pain. BMCL Digest. Bioorg. Med. Chem. Letters 26 (2016) 1103-1119.
- Bernhaus A., Ozswar-Kozma M., Saiko P., Jaschke M., Lackner A., Grusch M., Horvath Z., Madlener S., Krupitza G., Handler N., Erker T., Jaeger W.; Fritzer-Szekeres M., Szekeres T. Antitumor effects of KITC, a new resveratrol derivative, in AsPC-1 and BxPC-3 human pancreatic carcinoma cells. Investigational New Drugs 27 (2009) 393-401.
- Handler N., Brunhofer G., Studenik C., Leisser K., Jaeger W., Parth S., Erker T. „Bridged“ stilbene derivatives as selective cyclooxygenase-1 inhibitors. Bioorg. Med. Chem. 15 (2007) 6109-6118.
- In total 29 peer-reviewed scientific papers, 12 patents published

## BOOKS (author or co-editor)

- Comprehensive Medicinal Chemistry III, 3rd Edition 2017, Volume 2: Drug Discovery Technologies, Elsevier eBook ISBN: 9780128032015, Book ISBN: 9780128032008;
- Drug Selectivity: An Evolving Concept in Medicinal Chemistry (Methods and Principles in Medicinal Chemistry), Wiley-VCH ISBN-13: 978-3527335381 (10. Januar 2018);