



DR. NORBERT HANDLER, MBA

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PERSONAL BACKGROUND

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

PROFILE

- Registered "Consulting Engineer for Pharmacy" in Austria
- General Authorized and Certified Expert at the Trade Court Vienna for pharmaceutical chemistry
- 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; ¹⁸F labeling; biological evaluation (assay testing with [³H] 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

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

CURRENT AND FINISHED PROJECTS

- Project management:
 - design, implementation and control of development plans
 - small molecules, biologics, medical devices
 - quality and CMC issues
 - FP7 project "Flupharm"
- Evaluation and compilation of IMPD and module 3 (quality and CMC)
 - antibacterial ointment
 - iv cardiovascular drug
- Regulatory Advice: CMC, quality, drug development process
 - WHO drug development project
 - development project small molecule from biologic sources
 - medical device class 3
- Due diligence: CMC part
 - iv biologic
- Impurity and degradation profiling
 - oral antiviral drug
 - iv cardiovascular drug
 - iv narcotic drug
- Evaluation of manufacturing processes (oos events, CAPA etc.)
 - iv biologic
 - medical device class III
- Stability of drug substances and products
 - iv cardiovascular drug
 - iv biologic
- Project development and support
 - innovative pain drug
 - medical device class III
- Expert statements
 - quality of APIs
 - environmental risk
 - stability

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 27 peer-reviewed scientific papers, 12 patents published