DR. HELMUT BUSCHMANN

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BACKGROUND

- Nationality — German
- Date/place of birth — December 12th, 1960, Kaldenkirchen (now Nettetal)
- Marital status — Married, three children: Jonas (19th October 1988), Simon (12th March 1992), Hannah (5th September 1995)

PROFILE

- Senior management executive with over 25 years of international experience in drug discovery research and drug development in the Pharmaceutical/Biotechnology sectors with strengths in identifying, evaluating and integrating pre-clinical projects and transfer to clinical phase.
- Proven skills in discovery and development of innovative therapeutics for the treatment of Central Nervous System (CNS) disorders (e.g. pain, depression, schizophrenia, Alzheimer Disease, urinary incontinence) and metabolic disorders (obesity, diabetes) as well as cancer and antivirals.
- Strong expertise in managing the interfaces with chemistry, pharmacology, pharmacokinetics, toxicology and clinics with the goal to create innovative first-in-class New Chemical Entities (NCEs).
- In depth experience combining various research disciplines and approaches & coordinating drug discovery research in order to document a proof of innovative concepts for new drug candidates entering the clinical development phase.
- Developed and implemented innovative research and development strategies integrating state of the art technologies of modern drug discovery tools combining scientific expertise in pharmacology and chemistry with a strong commitment to the commercial aspects of the R & D process and an excellent understanding of the regulatory and intellectual property impact.

PROFESSIONAL EXPERIENCE

- Since June 2015

"Head of Chemistry, Pharmaceutical Development and Patent Affairs" at AiCuris GmbH & Co. KG, Friedrich-Aberst Str. 275, Building 302, 42147 Wuppertal

  - As member of the Management Team involved in planning, management and execution of the company strategy (e.g. evaluation of competitors and potential partners, preparation of collaborations, initiation and prioritization of internal projects, selection of development candidate molecules, budget planning and control).

- Since March 2014

"Managing Director at RD&C" RD&C Research, Development & Consulting GmbH, Consulting Engineers for Pharmacy, Vienna

  - RD&C Research, Development & Consulting GmbH is a privately-owned company founded in March 2014. The RD&C team covers a broad range of knowhow important for pharmaceutical drug development and is ready to provide solutions for difficult impurity issues backed-up by regulatory compliant argumentation.
  - Together with well-known partners for analytics, synthesis, bioinformatics and toxicology RD&C offers module-based services tailored to the individual requirements and needs for its clients.

- August 2010 – June 2015

"Chied Scientific Officer" at Savira pharmaceuticals GmbH; 1210 Vienna/Austria, Veterinärplatz 1

  - The CSO is part of the executive management team and in this role is, together with the other members of the executive management responsible for company strategy and overall operations.
  - In particular the CSO will have responsibility for internal and external scientific programs.
  - The CSO will assist the CEO for all other fields of Savita's operations.

- The CSO has all competences to define operational structures, operations and define strategic goals within his direct fields of responsibility.
- The CSO has all competencies to enforce operations within his line of report.
- Development and execution scientific strategy
- Building of partnerships and relationships with the scientific community
- Representation of Savira at scientific meetings
- Coordination external research programs
- Coordination of Savira's scientific publications and new patents
- Scientific evaluation of new projects
- Planning of experiments and analysis of data
- Responsible for Savita's Patent Portfolio (Filing and Prosecution)

- Since February 2009

Freelancer Senior Drug Discovery & Development Consultant

Consultancy of national and multinational biopharmaceutical companies in the field of Drug Discovery and Drug Development:

- Advice on strategic development
- Literature search concerning preclinical and patent issues, Advice on patent issues
- Preparing and evaluation of preclinical dossiers
- Cooperation with external specialists
- Chemometric analysis (multivariate data analysis, design of experiments)
- Expert reports and dossiers for drug approval (Quality Overall Summaries, Environmental Risk Assessments, Module 3 documentation)
- Chemistry, Manufacturing and Controls
- API Development
- Formulation Development
- Quality Management Support
- Project Management in a wide area of pharmaceutical projects with a focus on Chemistry, Manufacturing and Control (CMC)
- Very well experienced in Audits, successfully accomplished several audits of strongly regulated authority bodies, including Inspection as acting Auditor in Europe, US, Australia and Asia for API and drug product manufacturers.

- February 2002 – February 2009

"Research Director" at Laboratorios Dr. Esteve S.A, 08041 Barcelona/Spain, Avinguda de la Mare de Déu de Montserrat, 221

- Research Director, reporting to the CSO/CEO and responsible for all pre-clinical discovery, licensing, intellectual property and partnership activities, supporting API bulk synthesis and the clinical phases 1 and 2.
- Managed internal staff of currently 102 working (more than 50 persons with university degrees, 30 PhDs and 24 Bachelors of Science) as well as 10 part time employees in different positions with an annual budget of 29 M€ in 2007.
- In addition to the internal staff a broad outsourcing network contracting 20 additional people as FTEs at CROs as well as PhD students or postdoctoral fellowships at European universities or research centres in Spain, Germany, The Netherlands and France is managed.
- 4 Directors are reporting directly to the Head of Research: Head of Chemistry, Head of Pharmacology, Head of Pharmacokinetic and Toxicology, and Research Coordinator.
    - Medicinal Chemistry (Lead Optimisation and Candidate Profiling; early route finding).
    - Analytical Chemistry & Compound Logistics (including solid phase chemistry & plate management).
    - Computational Chemistry (Molecular Modelling, in silico screening, data bases, competitive intelligence).
    - *in vitro* Pharmacology (assay development; binding, functionality and selectivity; high throughput screening).
    - *in vivo* Pharmacology (lead and candidate profiling, efficacy).
    - Safety pharmacology (CNS & cardiovascular side effect profiling).
    - Animal facilities.
    - Early Drug Metabolism and Pharmacokinetic (in vivo and in vitro).
    - Toxicokinetic & Bioanalysis.
    - Toxicology (in vitro & in vivo).

- May 1992 – February 2002

"Head of Chemical Research" at Grünenthal GmbH, 52099 Aachen/Germany

  - Head of Chemical Research, reporting to the Head of Research managed 4 departments with a total staff of 90 people (22 PhDs) was responsible for all chemical activities in the R & D process from early Hit Finding to API Synthesis in pilot-scale for clinical studies.
  - Established a chemical research organization covering the field from Drug Design to API Synthesis under GMP and GLP regulation.
  - Managed strategic partnerships with international CROs to incorporate novel technologies within the chemical research process.

- September 1987 – May 1992

" Scientific Research Assistant" at Rheinisch-Westfälisch Technische Hochschule (RWTH) Aachen, Germany (BAT 2 position)

  - Management of advanced practical courses for students in Chemistry and Medicine.
  - Scientific management of diploma students in the research group of Prof. Dr. Dr. h.c. H.-D. Scharf at the Rheinisch-Westfälisch Technische Hochschule Aachen.
  - Examiner in diploma exams for organic chemistry.

EDUCATION

- MAY 1987 – MAY 1992 **PhD**

Ph.D. in Organic Chemistry from the Rheinisch-Westfälisch Technische Hochschule Aachen (research group of Prof. Dr. Dr. h.c. H.-D. Scharf); *summa cum laude*; Dissertation Title: "*From the diastereoselective Paternó-Büchi reaction to the Isoinversion Principle - a General Model of Chemical Selectivity".*

- October 1986 – May 1987 **Diploma Thesis**

Diploma thesis ("Diplom-Chemiker") in the research group of Prof. Dr. Dr. h.c. H.-D. Scharf at the Rheinisch-Westfälisch Technische Hochschule Aachen; title of the diploma thesis: "*The Synthesis of (+)-8-Phenylmenthol*

- OCTOBER 1986 **Diploma examination**

Rheinisch-Westfälisch Technische Hochschule Aachen

- OCTOBER 1983 **Diploma Pre-examination**

Rheinisch-Westfälisch Technische Hochschule Aachen

- JULY 1979 – MARCH 1981 **Civil Service ("Zivieldienst")**

Psychiatrical hospital for children, Maria Helferin, Nettetal-Leuth, Germany

- JUNE 1979 **Final high-school examination** ("Abitur")

"*Städtisches Gymnasium*", Viersen, Germany.

SPECIAL SKILLS

- Languages: Fluent in German (mother tongue) and English (fluent, advanced level), Conversant in French, Spanish (intermediate level).

PERSONAL INTERESTS

- Cooking (I love to cook for friends, to modify recipes and to provide an individual note)
- Collector of international cooking books
- Youngest history and evolution of theories of states
- History of science (evolution of scientific theories and their relation to ancient natural science)
- Model car collector (oldtimer and modern car types, historical motor trucks)
- Woodworking and to design and build furniture of timber.

INTERNATIONAL ACADEMIC ACTIVITIES

- Lead and co-authored 126 Original articles in peer reviewed journals or book chapters.
- Listed as inventor on 249 patent application families
- Invited lectures in 98 international congresses.
- Author and Editor of 5 books:
  - H. Buschmann, H.-D. Scharf, *„Stereochemie in der Organischen Synthese: Reaktionen, Modelle, Konzepte*“, 1002 pages, libry, books on demand, ISBN 3-89811-518-6, publication date: june 2000; English version is in preparation.
  - H. Buschmann, T. Christoph, E. Friderichs, C. Maul, B. Sundermann, „ *Analgesics - From Chemistry & Pharmacology to Clinical Application*“ 604 pages, Wiley-VCH, 2002, ISBN-3-527-30403-7.
  - H. Buschmann, J. Holenz, A. Parraga, A. Torrens, J.M. Vela, „ *Antidepressants, Antipsychotics, Anxiolytics - From Chemistry & Pharmacology to Clinical Application*“, 2 Volumes, >1200 pages, Wiley-VCH, 2007.
  - 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);
- Series Editor of Book Series “Methods and Principles in Medicinal Chemistry”:
  Established in 1993, the series *Methods and Principles in Medicinal Chemistry* has become a crucial source of information within the medicinal chemistry community and beyond.
- Scientific Advisory Board, **Leibniz-Institut fuer Katalyse (LIKAT),** Rostock & Berlin, Germany (2002 – present). The Leibniz Institute for Catalysis is the biggest publicly funded research institute in Europe performing application-oriented research in the field of catalysis (www.catalysis.de).
- Scientific Advisor of **“The Institute of Chemical Research of Catalonia” (ICIQ)** to bring basic research results to pharmaceutical applications. ICIQ conceived with the aim of becoming a reference centre for Chemistry within the European Research Area, is the research institute that provides the talent and leadership needed to improve citizens' quality of life through the application of chemistry at the frontiers of knowledge (www.catalysis.de) .
- Member of **“Research Director Group”** (2004 – September 2008) inside the EFPIA (European Federation of Pharmaceutical Industries and Associations). This working group is responsible for defining the Strategic Research Agenda (SRA) and together with the European Commission the Innovative Medicine Initiative (IMI). The IMI is a unique pan-European public and private sector collaboration between large and small biopharmaceutical companies, governments, academia and patients to support the faster discovery and development of better medicines with an estimated investment of over 440 M€ per year for 7 years starting in 2008 (www.imi-europe.org).

AWARDS

- Borchers medal from the Rheinisch-Westfälisch Technische Hochschule Aachen for best Ph.D. thesis.
- R&D Award 2003-2004, Laboratorios Dr. Esteve.
- IUPAC-Fischer Price Award for Medicinal Chemistry 2014 (http://www.iupac.org/news/news-detail/article/helmut-buschmann-is-awarded-the-2014-iupac-richter-prize.html)

Special expertise in Statistical Analysis

- Chemometric and multivariate analyses for drug substance and drug product development: Process Analytical Technology (PAT), Design of Experiment (DOE) and Quality by Design (QbD).
- Statistical evaluation of stability data (Out of Specification (OOS) analysis) according ICH and Guidance for Industry guidelines.

GMP Audit Experience

- Very well experienced in Audits, successfully accomplished several audits of strongly regulated authority bodies, including Inspection as acting Auditor in Europe, US, Australia and Asia for API and drug product manufacturers.

Aachen, May 2018