

Curriculum vitae



Dirk Benedikt Strickmann

Dr. rer. nat. (\cong PhD in Pharmaceutical Chemistry)

Diplom-Chemiker (\cong MSc in Chemistry)

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Born on 20.08.1970 in Steinfurt (Germany)

Married, two children

Professional experience and major achievements

Since 05|2020

DBS Consulting, Purkersdorf, Austria

Consultant

I offer consulting in the areas of bioanalysis (e.g. bioanalytical CRO management, review of bioanalytical documents), small molecule drug development (planning of ADME/DMPK and DDI studies through all phases of non-clinical and clinical development), scientific writing (INDs, IBs, NDAs, MAAs, etc.), due diligence, research facility organization (e.g. support during planning of new or modernization of old research facilities), and management consulting (e.g. corporate resilience optimization like pandemic & blackout planning, risk assessment, Black Swan event planning, interim CEO, etc.).

10|2024 - 12|2025

Rockfish Bio AG, Vienna, Austria

Director DMPK/ADME

Rockfish Bio (RFB) AG Vienna, Austria

I helped setting up the non-clinical ADME/DMPK program for novel small molecule senolytics including plasma and organ PK, drug metabolism, drug transporters, and plasma protein binding. I was member of the research & development team. Furthermore, I set up the HSE concept for Rockfish Bio.

09|2023 - 12|2025

InnoFly BioCenter GmbH, Vienna, Austria

June 2024 – Dec. 2025

Managing Director

InnoFly BioCenter (IBC) GmbH, Vienna, Austria

Sept. 2023 – Dec. 2025

Site Head, Managing Director in terms of Trade Law

InnoFly BioCenter (IBC) GmbH, Vienna, Austria

I built up and managed IBC's laboratory facility in Leberstrasse 20, 1110 Vienna hosting four small biotechnology companies and one accounting company.

02|2006 - 07|2023

Nabriva Therapeutics GmbH, Vienna, Austria

May 2023 – July 2023

Freelancer / Freier Dienstnehmer

Nabriva Therapeutics GmbH, Vienna, Austria

Supporting the shutdown process of the site in Vienna

June 2021 – May 2023

Managing Director / Handelsrechtlicher Geschäftsführer

Nabriva Therapeutics GmbH, Vienna, Austria

Corporate responsibility for the Nabriva Therapeutics site in Vienna including the day-to-day business with a focus on organizational, technical as well as facility, safety, and security related aspects.

- Sept. 2016 - May 2023 **Senior Director DMPK**
Nabriva Therapeutics GmbH, Vienna, Austria
 Responsible for all internal tasks related to bioanalytical aspects and several ADME/DMPK aspects (e.g. drug metabolism, drug transporters, and plasma protein binding) and head of a bioanalytical laboratory with up to two staff scientists. Furthermore, responsible for the planning and realisation of bioanalytical phases/studies for all non-clinical and clinical studies, as well as external studies on metabolism and drug transporters. Co-authoring for an approved NDA (FDA), an approved NDS (Health Canada), and an approved MAA (EMA) for Xenleta®.
 Member of the non-clinical and clinical research & development teams.
- Jan. 2015 - May 2023 **Managing Director in terms of Trade Law / Gewerberechtlicher Geschäftsführer**
Nabriva Therapeutics GmbH, Vienna, Austria
 Responsible for Nabriva's compliance with the Austrian Trade Law as well as several other laws and bylaws like the Health and Safety Executive Law, the Premises Permit (Betriebsanlagengenehmigung) for the site, the Austrian Chemical Act, the Personal Protection Equipment Safety Regulations, the Austrian Ordinance on Flammable Compounds, etc.
 Direct supervisor for the facility manager.
- Aug. 2012 - Oct. 2015 **Biology Lead Discovery Unit**
Nabriva Therapeutics AG, Vienna, Austria
 Responsible for the coordination of biological activities (bioanalytical laboratory, microbiology laboratory, and *in vivo* pharmacology laboratory) in the discovery unit and counterpart to Chemistry Lead Discovery Unit.
- Aug. 2011 - Aug. 2016 **Director Bioanalytics**
 Mar. 2007 - Aug. 2011 **Principal Scientist - Bioanalytics**
Nabriva Therapeutics AG, Vienna, Austria
 Responsible for all internal and external tasks related to bioanalytical aspects and several ADME aspects (e.g. metabolism and plasma protein binding) and head of a bioanalytical laboratory with two technicians
- Dec. 2007 - Jan. 2008 Relocation and establishment of the bioanalytical laboratory (*Nabriva Therapeutics AG*) in a new research facility.
- Feb. 2006 - Mar. 2007 **Principal Scientist - Analytical Chemistry**
Nabriva Therapeutics Forschungs GmbH, Vienna, Austria
 Head of two analytical laboratories
 Responsible for bioanalysis, pharmaceutical analysis, QC and interim head QA.
- 01|2002 – 01|2006 Sandoz GmbH - Antibiotic Research Institute (ABRI)**, Vienna, Austria
- Oct. 2002 - Jan. 2006 **Head of analytical laboratory**
Sandoz GmbH - Antibiotic Research Institute (ABRI), Vienna, Austria
 Responsible for bioanalysis, pharmaceutical analysis and QC.
- Jan. 2003 Approval of GLP status for the analytical laboratories of *ABRI Vienna (Sandoz GmbH)* by the *Austrian Federal Ministry of Social Security, Generations and Consumer Protection*.
- June 2002 - Jan. 2003 Preparation for GLP approval by the *Austrian Federal Ministry of Social Security, Generations and Consumer Protection* for the analytical laboratories of *ABRI Vienna* within very short time.
- Jan. to Oct. 2002 **Research Associate**
Sandoz GmbH - Antibiotic Research Institute (ABRI), Vienna, Austria
 Implementation and operation of a new LC-MS ion trap system.

- 01|2001 – 12|2001** **Dept. of Inorganic Chemistry - Bioinorganic and Complex Chemistry, University of Vienna, Austria**
- Postdoctoral Fellowship**
Dept. of Inorganic Chemistry - Bioinorganic and Complex Chemistry
University of Vienna, Austria
 Lise-Meitner scholarship of the *Austrian Science Fund (FWF)*.
 Implementation and operation of a new LC-and CE-MS ion trap system.
 Tutor: Prof. Dr. Dr. Bernhard K. Keppler
- 10|1996 – 12|2000** **Westfälische Wilhelms-Universität / University of Münster, Germany**
- Nov. 2000 - Dec. 2000 **Traineeship in Forensic Chemistry**
University Hospital Münster, Chemical and Toxicological Department,
Münster, Germany
 Supervisor: Dr. Helga Köhler
- June 1997 - Dec. 2000 **Research Associate**
Dept. of Pharmaceutical Chemistry, University of Münster, Germany
 Supervisor: Prof. Dr. Gottfried Blaschke
- Oct. 1996 - May 1997 **Research Assistant**
Dept. of Pharmaceutical Chemistry, University of Münster, Germany
 Supervisor: Prof. Dr. Gottfried Blaschke

Professional activities and further trainings

- July 2020 EMA approval for Xenleta® (Lefamulin)
- July 2020 Health Canada approval for Xenleta® (Lefamulin)
- Aug. 2019 FDA approval for Xenleta® (Lefamulin)
- May 2019 Marketing authorization application (MAA) for lefamulin, a first-in-class, semi-synthetic pleuromutilin antibiotic for the treatment of community-acquired bacterial pneumonia submitted to the U.S. FDA:
 Co-authoring for the NDA modules 2.4, 2.6.1, 2.6.4, 2.6.5, 2.7.1, 2.7.2, and 2.7.4
- Dec. 2018 New Drug Application (NDA) for lefamulin, a first-in-class, semi-synthetic pleuromutilin antibiotic for the treatment of community-acquired bacterial pneumonia submitted to the U.S. FDA:
 Co-authoring for the NDA modules 2.4, 2.6.1, 2.6.4, 2.6.5, 2.7.1, 2.7.2, and 2.7.4
- 21 Mar. 2018 Successful audit of the facility by the municipal authorities of the city Vienna acc. to § 338 GewO 1994 (industrial code)
- 20 - 24 Nov. 2017 Successful self-inspection of the facility acc. to § 82b GewO 1994 (industrial code)
- 04 - 06 Dec. 2012 Training: "Introduction to Phoenix WinNonlin" (Simon Davis, *Pharsight*, London, GB)
- 30 Oct. 2012 Training: "Good Clinical Practice" (Dr. Laura Brown, *LB Training and Development Ltd*, Vienna, Austria)
- 29 - 30 Nov. 2011 Training: "Method Development" (LC-MS(/MS)) (Dr. Axel Römer, *A&M GmbH*, Vienna, Austria)
- 05 May 2011 Training: "Good Clinical Practice" (Dr. Sherry Armstrong-Wilkinson, *Rooster Training Solutions*, Vienna, Austria)

May 2010	Submission of comments on 'Guideline on validation of bioanalytical methods' (EMA/CHMP/EWP/192217/2009) in collaboration with the <i>Bioanalytik Forum Bergheim (BFB)</i>
10 May 2010	Training: "Good Clinical Practice" (covering ICH-GCP and relevant parts of the CFR) (Dr. Nina Schiestl, <i>Clinical Consulting</i> , Vienna, Austria)
07 July 2008	Training: "Introductory GCP and Safety" (Dr. Karen Bruckmann and Dr. Perrine Paul Clerget, <i>Nabriva Therapeutics AG</i> , Vienna, Austria)
2005 - today	Co-author of several IMPDs, IBs, INDs, and clinical trial protocols (submitted successfully to Austrian, British, German, and US authorities)
2005 - 2016	Cooperation in the <i>Bioanalytik Forum Bergheim (BFB)</i> , an expert group for bioanalytical method validation, Bedburg, Germany (organized by A&M GmbH)
09 - 10 May 2006	Training: „GMP/FDA-gerechte Herstellung klinischer Prüfmuster“ (<i>Forum - Institute for Management</i> , Mannheim, Germany)
25 - 26 June 2002	Training: „Theory and Practice of GLP“ (<i>Forum - Institute for Management</i> , Cologne, Germany)
03 Mar. 2002	Training: Basic cGMP and GLP course (Dr. Walter Goldstein, <i>Sandoz GmbH</i> , Kundl, Austria)

Participation in recent symposia and conferences

15 Nov. 2022	ICH M10 - Workshop towards harmonised implementation of the ICH M10 Guideline organized by the European Bioanalysis Forum (EBF), Barcelona, Spain
16 to 18 Nov. 2022	15 th Open Meeting of the EBF, Barcelona, Spain
24 to 26 Nov. 2021	14 th Open Meeting of the EBF, Barcelona, Spain
19 to 22 Nov. 2019	12 th Open Meeting of the EBF, Barcelona, Spain
20 to 22 May 2019	ICH M10 - Public consultation & industry feedback towards a science based global bioanalytical guideline organized by the EBF, Barcelona, Spain
21 to 23 Nov. 2018	11 th Open Meeting of the EBF, Barcelona, Spain
15 to 17 Nov. 2017	10 th Open Meeting of the EBF, Barcelona, Spain
16 May 2017	1 st Workshop on Application of Quantitative HRMS (1st WQHRMS), Muttenz Switzerland
21 to 22 June 2016	7 th International Conference on Clinically Relevant Drug Transporters, Berlin, Germany
10 to 13 May 2016	Transporter Conference 2016, Meet the Experts, Budapest, Hungary
10 to 13 May 2014	24 th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID 2014), Barcelona, Spain
03 to 04 Apr. 2014	Transporter Conference 2014, Meet the Experts, Budapest, Hungary
20 to 22 Nov. 2013	6 th Open Meeting of the EBF "Moving Forward Together", Barcelona, Spain

Education

- Jan. 2001 - Dec 2001 **Postdoctoral Fellowship**
Dept. of Inorganic Chemistry - Bioinorganic and Complex Chemistry, University of Vienna, Austria
Lise-Meitner scholarship of the Austrian Science Fund (FWF).
Supervisor: Prof. Dr. Dr. Bernhard K. Keppler
- 12 July 2000 **Dr. rer. nat. in Pharmaceutical Chemistry (≅ PhD)**
Dept. of Pharmaceutical Chemistry, University of Münster, Germany
- Oct. 1996 - July 2000 **Doctoral thesis**
Dept. of Pharmaceutical Chemistry, University of Münster, Germany
Supervisor: Prof. Dr. Gottfried Blaschke
- Oct. 1990 – July 1996 **Studies of Chemistry** (Diplom-Chemiker, ≅ MSc),
University of Münster, Germany

Publications and patents

List of publications and patents are available upon request.

Additional skills

- General:
- **Safety expert for life science laboratories**
 - Managing Director in terms of Trade Law (Gewerber. GF acc. to GewO),
 - Safety officer
 - Safety representative (Sicherheitsvertrauensperson acc. to SVP-VO),
 - Fire warden (Brandschutzwart acc. to TRVB 117 O),
 - Active firefighter and dangerous goods officer at Volunteer Fire Department in 3002 Purkersdorf
 - **Expert for corporate resilience**
 - Epidemic/pandemic, blackout, and Black Swan event planning
- Techniques:
- Chromatographic methods: LC-UV, LC-MS(/MS), IC, GC-FID.
 - Spectrometric methods: MS (Ion trap MS, MS/MS, ESI, APCI).
 - Electrophoretic methods: CE (chiral/achiral), CE-MS, CEC, CEC-MS.
 - Miscellaneous: handling and preparation of biological samples, quantification of drugs in tissue samples (plasma, blood, urine, feces, organs), validation of analytical methods, PK parameter calculations with WinNonlin.
- Languages:
- German (mother tongue)
English (fluent)
- IT:
- MS WORD, EXCEL, ACCESS, POWERPOINT, Phoenix™ WinNonlin® v 6.3 (Pharsight), Veeva Vault

References

References, certificates, and letters of recommendation are available upon request.