

Sandor BERNATH, MSc, Dr. Univ., PhD, MBA

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KEY SKILLS

Over 30 years of experience in academia and life science industry. Directed one original drug development project from lead selection to Phase 2 clinical trials. Wrote numerous expert reviews for marketing authorization applications; compiled and submitted clinical trial applications, orphan designation applications, and PIP applications. Experience in interacting with the health authorities in the EU including the EMA. Taught neuropharmacology at University of Pittsburgh, USA and Eötvös Loránd University, Budapest, Hungary. Published 42 papers (18 in peer-reviewed SCI journals).

PROFESSIONAL EXPERIENCE

FontaMed Consulting Ltd., Telki, Hungary; Rome, Italy

FontaMed provides expert documentation to EU, US, and Australian companies applying to drug agencies such as EMA (EU), FDA (US), TGA (Australia), etc. for human clinical trial permission or drug marketing authorization.
www.fontamed.com

Owner Managing Director

2002 –

- Member of an International Pharmaceutical Advisory Group consisting of the former Global Regulatory Vice President of Bayer AG, the former Medical Director of Novo Nordisk A/S, and former R&D Director of Merck Frosst Canada Inc.
- Extensive experience in compiling Common Technical Documentation for drug registration; preparing complete clinical trial application package; writing expert reviews such as nonclinical & clinical overviews, IMPD, Investigator's Brochure, etc.

Kinexum Services LLC, Harpers Ferry, WV, USA

Independent Consultant

2015 –

- Writing expert reviews and preparing regulatory submissions

N-Gene Research Laboratories, Inc., New York, NY, USA; Budapest, Hungary

US drug development company with an affiliated company in Hungary www.ngene.us

Chief Operating Officer, Hungary

1997 –

- Supervising that the company's pre-IND and IND efforts meet the requirements of EU Directives, FDA and ICH Guidelines.

Biorex Research & Development Co., Budapest, Hungary; London, UK

Deputy Director of Science

1994 – 97

- Conducted license negotiations & prepared contractual agreements with multinational pharmaceutical companies such as Bayer AG, Ely-Lilly, Pfizer, etc.
- Directed implementation of ISO 9001 quality control system;
- Coordinated Phase 1 and 2 multi-center clinical trials in the UK and Hungary. Filed INDs to the MCA (London, UK) and OGYI (Budapest, Hungary).

University of Pittsburgh, Dept. of Behavioral Neuroscience, Pittsburgh, PA, USA

Research Assistant Professor

1992 – 94

- Developed combined methods of pharmacology and electrophysiology to study neuronal transmission.
- Had 3 hours per week undergraduate teaching responsibility.

Leader, Neurochemistry Group

1990 – 92

Research Associate

1986 – 89

Inst. of Experimental Medicine, Hungarian Academy of Sciences, Budapest, Hungary

Senior Research Associate

1990 – 92

Research Associate

1986 – 89

TANÉRT CO., Budapest, Hungary

Research Associate

1979 – 84

EDUCATION

MBA	Brunel University, Uxbridge, London, UK	2003
PhD	<i>in Biological (Pharmacological) Sciences</i> Hungarian Academy of Sciences, Budapest, Hungary	1995
University Doctorate	<i>in Anatomy and Cell Biology with Summa cum laude record</i> Eötvös Loránd University, Budapest, Hungary	1981
MSc	<i>in Biology and Chemistry with excellent record</i> Eötvös Loránd University, Faculty of Sciences, Budapest, Hungary	1979
Courses	Translator and Interpreter in English Eötvös Loránd University, Budapest, Hungary (1 semester)	1997

AWARDS

Honorary Reader , University of Debrecen, Faculty of Medicine, Hungary	2005
Green Card in the USA upon Preference "A" as an "Outstanding Scientist"	1993
Central Research Development Award, University of Pittsburgh, USA	1993
Sheldon Novick Award, Tourette Syndrome Association, USA	1993
First Prize, National Teaching Aids Competition (see <i>Ministry of Education Bulletin [Művelődési Közlöny] XIV, 20, 1980</i>)	1980

LANGUAGES

Hungarian	(Native)
English	(Advanced Type "C" State Language Certificate; TOEFL score 623)
Italian	(Full Working Proficiency)
French	(Basic Type "C" State Language Certificate)

TEACHING EXPERIENCE

Psychopharmacology (credit 2) Eötvös Loránd University, Dept. of Comp. Physiology, Budapest, Hungary	1996 – 97
Neuropharmacology (Drugs and Behavior #7035; credit 3) University of Pittsburgh, Dept. of Behavioral Neuroscience, USA	1991 – 92

PUBLICATIONS

42 publications (18 in peer-reviewed SCI journals). Total citations: > 500

COMPUTER SKILL

Microsoft Office, Adobe Photoshop

OUTSIDE INTEREST

Nature photographer (www.photo.net/bernath)