



Curriculum Vitae

Personal information **Ute Friedel**

Work experience

6/2023-today Clinical assessor

Paul-Ehrlich-Institut, Langen near Frankfurt/Main (Germany)

10/2022-05/2023 Freelance medical writer and consultant

Dr. Ute Friedel – Scientific Solutions, Bad Homburg (Germany)

10/2016-06/2022 Manager health technology assessment

Lilly Deutschland GmbH (affiliate of Eli Lilly and Company), Bad Homburg near Frankfurt/Main (Germany)

- German benefit assessment dossiers in compliance with the Act on the Reform of the Market for Medicinal Products (Arzneimittelmarktneuordnungsgesetz)

- written statements for submission to the German Joint Federal Committee (Gemeinsamer Bundesausschuss)

- (early) advice meetings at the German Joint Federal Committee (preparation of pertinent documents and meeting attendance)

- white papers

- systematic literature search (Cochrane methodology)

- selection of indications: hepatocellular carcinoma, non-small cell lung carcinoma (including knowledge of tissue agnostic antineoplastic agents), gastric carcinoma, ankylosing spondylitis, diabetes, migraine, dementia, osteoporosis etc.

08/2008-09/2016 (Senior) advisor nonclinical & clinical affairs

PharmaLex GmbH, Friedrichsdorf near Frankfurt/ Main (Germany)

- medical writing according to ICH-GCP guidelines and other relevant laws and regulations:

- clinical and nonclinical modules in compliance with the Notice to Applicants Volume 2B (mainly clinical and non-clinical overviews)

- reclassification clinical overviews (A Guideline on Changing the Classification for the Supply of a Medicinal Product for Human Use)

- orphan medicinal product designation dossiers (Regulation EC No 141/2000)

- briefing documents for scientific advice meetings and attendance of scientific advice meetings

- medical expert statements

01/2007-06/2007 Research associate, German Sports University (Deutsche Sporthochschule Köln), Cologne (Germany)

co-writer of an expert opinion on gene doping (gene therapy) for the Office of Technology Assessment at the

German Parliament (Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag)

11/1996-10/1997 Marketing assistant, SectorCon Ingenieurgesellschaft für System- und Softwaretechnik mbH, Berlin (Germany)

- software support service for hospitals and funding organisations

- software support service for commercial websites

- writing documents (circular letters, individual letters, brochures)

Education and training

1/2008-03/2008 Internship clinical evaluation at the German Federal Institute for Drugs and Medical

Devices (Bundesinstitut für Arzneimittel und Medizinprodukte), Bonn (Germany)

- evaluation of formal and scientific aspects of clinical trial applications (completeness, validity, and compliance with relevant regulatory guidance)

10/2007-12/2007 Postgraduate training in clinical research at the mibeg Institute of Medicine (mibeg-Institut Medizin), Cologne (Germany)

subjects: basic toxicology, pharmacology, and medicine; clinical trials and clinical evaluation; national and international regulatory guidance; scientific writing, medical terminology, medical English; biometry, medical statistics, IT in clinical trials; health economics

1993 – 1997 Postgraduate studies of economics for engineers and natural scientists, Open University, Hagen (Germany)

1995 - 1997 specialisation on marketing

1995 pre-diploma (German equivalent to bachelor's degree)

1989 – 1993 Doctoral thesis in biochemistry, Max-Planck-Institute of Biophysics, Frankfurt/Main (Germany),

team of Nobel laureate Prof. Dr. Hartmut Michel

1984 – 1989 Studies of biology (major subject: biochemistry), diploma (German equivalent to master's degree), Johann Wolfgang Goethe-University, Frankfurt/Main (Germany)

Additional information

Publications

Friedel U, Wolbring G, Wohlfart P, Cook NJ. The sodium-calcium exchanger of bovine rod photoreceptors: K(+)-dependence of the purified and reconstituted protein. *Biochim Biophys Acta*. 1991 Jan 30;1061(2):247–52.

Reiländer H, Achilles A, Friedel U, Maul G, Lottspeich F, Cook NJ. Primary structure and functional expression of the Na/Ca,K-exchanger from bovine rod photoreceptors. *EMBO J*. 1992 May;11(5):1689–95.

Achilles A, Friedel U, Haase W, Reiländer H, Cook NJ. Biochemical and molecular characterization of the sodium-calcium exchanger from bovine rod photoreceptors. *Ann N Y Acad Sci*. 1991;639:234–44.

Reid DM, Friedel U, Molday RS, Cook NJ. Identification of the sodium-calcium exchanger as the major ricin-binding glycoprotein of bovine rod outer segments and its localization to the plasma membrane. *Biochemistry*. 1990 Feb 13;29(6):1601–7.

Projects
Memberships
Other Relevant Information