Klaus Eckhardt, MD
born on 15. July 1962

Konrad-Adenauer-Ufer 63
50668 Köln
k_eckhardt@web.de
Tel.: +49 171 6797272

Curriculum Vitae

Since Apr 2022 **Founder + Managing Director Con-Eckt Consulting,** Cologne

Feb 20 – Mar 22 **Independent - Manuscripts on Approval of COVID-19 Vaccines**
Evidence-time dilemma in a pandemic with high mortality. Clinical and Translational Science, September 2021

Apr 17 – Jan 20 **Medical Director** Area Inflammation, UCB Biosciences GmbH
- Patient Preferences in Clinical and Regulatory Decision-Making
  - Planning pilots for Cimzia (Rheumatoid Arthritis), Bimekizumab (Psoriasis, Hidradenitis suppurativa); rozanolixizumab (Myasthenia)
- Patient Focused Drug Development – Concepts for Implementation

Oct 15 – Mar 17 **Global Regulatory Lead**, Early Projects, UCB Biosciences GmbH
- Lead regulatory subteams for projects in neurologic indications
- Regulatory strategy to approval in key regions (US, EU, Japan, China)
  - Expedited pathways to approval
  - Orphan designation, Paediatric development plans (PIP, PSPs)
  - First in human studies

Jan 09 - Sep 15 **Medical Director, CNS Practice,** UCB Biosciences GmbH
- Study Physician on Briviact and Vimpat Phase 3/4 studies (09 – 15)
- Regulatory/Medical Lead, Xyrem EMA submission (Fibromyalgia) in 10
- Medical Input on Briviact submission to EMA/FDA in 14, approved in 16
- Leading/organizing internal workshops on economic perspectives in clinical development (including HTA; EPIC) as Co-Chair (2011 – 2015)

May 05- Dec 08 **Associate Director Regulatory Affairs,** UCB Biosciences GmbH
EU Regulatory Lead for Vimpat (Lacosamide)
- Partial-onset seizures – EMA Submission 07, approval 08
- Diabetic neuropathic pain – EMA submission 07, withdrawal 08

Oct 01 – Apr 05 **Clinical Trials Unit, BfArM** (Federal Institute for Drug, Medical Devices) **Head of Clinical Pharmacology** (Dec 04 – Apr 05), Bonn
- Lead of assessment/authorisation of phase 1-4 trials; GCP Inspections
- Member of EMA Pharmacokinetic working party

Sep 00 – Sep 01 **Scientific Assistant in Clinical Neuropharmacology**, Neurology Clinic, University, Freiburg, Germany
Clinical/Experimental research on mechanism of action of CNS drugs

Jan 95 – Aug 00 **Scientific Assistant at Clinical Pharmacology Institute** at Dr. Margarete Fischer-Bosch Institute, Stuttgart (Prof. Dr. Eichelbaum)
- Conduct of phase 1 studies on pharmacogenetics/-kinetics of opioids
- Conduct of phase 1 bioequivalence studies (Verapamil)
- Signal transduction research on opioid-/cannabinoid receptors on abuse (Weizmann Institute from Nov 98 to Jan 20 Rehovot, Israel)

Education

June 1981	**High School Graduation, Schwalmschule, Treysa** (3.6.1981)
1983-1988	**Studies in Pharmacy at Philipps University, Marburg**
June 1988	**Pharmacy degree and Licensed Pharmacist** (15.6.1988)
1988-1994	**Studies of Medicine at Albert-Ludwigs-University, Freiburg** M.D. thesis at Institute of Pharmacology (Prof. Dr. T. Feuerstein) *Modulation of GABA in the Nucleus Caudatus of the rabbit*
Sep 1995	**Medical Doctorate** (13.9.1995)
July 1996	**Medical License** (1.7.1996)
Feb 2001	**Board Certification as Clinical Pharmacologist** (15.2.2001)
2002 – 2004	**Master Course *Drug Regulatory Affairs*, Rheinische Friedrich-Wilhelms-University Bonn, Germany**
2004	**Master *Drug Regulatory Affairs*** (13.8.2004)
Jan-Nov 2020	**Basic Training Course on European Patent Law (CEIPI), Rome**

Further qualifications

Since 2004	**Lecturer at Master Course Drug Regulatory Affairs** Rheinische Friedrich-Wilhelms-University Bonn
1997 - 2006	**Training courses in clinical research and regulatory affairs** • Seminar *Leiter Klinische Prüfung (AMG)* University Tübingen, • GCP-inspectors Training Seminar (10/2003, Ede, Netherlands) • DIA IND Training Course, February 2006, San Francisco, USA • DIA NDA Training Course, March 2006, Atlanta, USA

Memberships

- Drug Information Association (DIA)
- American Society Clinical Pharmacology & Therapeutics (ASCPT)
- German Society of Regulatory Affairs (DGRA)

Additional qualifications

- Knowledge in foreign languages: English, Italian, Spanish
- Detailed experience in Word, Excel, Powerpoint, MS Access

Köln, April 2022