

## **Curriculum Vitae Professor Hans P. Zenner**

**Clinical Education.** 1972 M.D. University of Mainz, Germany; Studies in Paris, France. 1974 Dr. med. in oncological research.

**Clinical Career.** 1973 Medical Assistant at University of Heidelberg, Germany. 1974-1976 Post-Doc at the Dept. of Biochemistry, University of Würzburg, Germany. 1976 Residency Dept. of ORL, Head&Neck Surgery, University of Würzburg; 1981 Habilitation in Oncology, Oberarzt (Consultant) and Docent University of Würzburg. 1985 Visiting Scientist at Michigan University Ann Arbor, USA, and at Washington University St. Louis, USA. 1986 Professor of ORL, Head&Neck Surgery, University of Würzburg; 1988-2016 Distinguished Professor of ORL, HeadNeck Surgery, and Chairman Dept. of ORL, Head&Neck Surgery, University of Tübingen, Germany.

**Clinical Evaluation.** Since 1996 CERs and risk analyses. 1986-2016 Director Clinical Trials according to MPG and AMG. 2017-2018 Chairman MDD/AIMDD/MPG Ethics Commission Tübingen, before that member. Since 2016 Senior Clinical Evaluator and CEO of HPZenner CER Services.

**Honorary Offices.** 2009 and 2010 President German Association of Physicians and Scientists (GDNÄ). Since 2010 Board Member, German Natl.Acad.Sci. Leopoldina.

**Awards.** Various awards including Leibniz Prize, Humboldt Medalist. Several International Memberships of Honor and several Doctorates honoris causa.

**Clinical Research Focus.** Group leader Development and Clinical Trials Medical Devices including the Tübingen Titanium Prostheses (TTP), totally implantable hearing aids, cochlear implant technology, and audiological devices.

**Publications.** More than 300 Medline listed publications, h index 61, 8 books, around 70 patent publications.

## **Fulfillment of MEDDEV 2.7/ rev 4 requirements**

### ***Research methodology (including clinical investigation design and biostatistics):***

1996-today: Head and designer/codesigner of several clinical trials according to AMG, MPG, AIMDD, FDA including codesign of statistics, clinical and statistical evaluation and publication as well as negotiations with BfArM.

Former Chairman of Ethics Commission Tübingen according to § 22 MPG (Code DE/EKBW06), University of Tübingen Medical School; formal evaluation of more than 1000 clinical studies according to AMG, MPG, AIMDD, BO including biostatistics.

### ***MEDDEV 2.7/1 revision 4, page 15 of 65 - information management (e.g. scientific background; experience with relevant databases such as Embase and Medline):***

1976-today: university researcher (Germany and US) and later Director of medical research; more than 300 original Medline listed publications requiring comprehensive use of relevant databases such as Embase and Medline. Hirsch index (h-index) 61.

### ***Regulatory requirements; and - medical writing (e.g. post-graduate experience in a relevant science or in medicine; training and experience in medical writing, systematic review and clinical data appraisal):***

1974-today postgraduate training and experience in Medicine including 1988-2016 as Chairman of the Department of ORL, Head&Neck Surgery, The University of Tübingen, Germany. More than 300 original Medline listed publications and additional reviews both requiring comprehensive scientific and medical writing including data appraisal.

### ***With respect to the particular device under evaluation, the evaluator should in addition have knowledge of: - the device technology and its application; - diagnosis and management of the conditions intended to be diagnosed or managed by the device, knowledge of medical alternatives, treatment standards and technology (e.g. specialist clinical expertise in the relevant medical specialty):***

ENT specialist, Distinguished Professor of ENT, Head&Neck Surgery  
Past Chairman University of Tübingen Dept. of ENT, Head&Neck Surgery

### ***The evaluator should have at least the following training and experience in the relevant field:***

#### ***- a degree from higher education in the respective field and 5 years of documented professional experience:***

1972 M.D. in Medicine, 1974 Dr.med. in Oncology, 1980 Specialist in ENT, Head&Neck Surgery, 1981 Dr. med. habil. in Oncology, 1974- today professional experience as physician&surgeon

#### ***- or 10 years of documented professional experience if a degree is not a prerequisite for a given task:***

1974- today professional experience as physician&surgeon