



Professor Dr.med. Dr. h.c. Manfred Wirth
Senior Clinical Evaluator Urology/Nephrology

Curriculum Vitae

Clinical Education. 1976 M.D., Germany, 1977 Dr. med.

Clinical Career. 1976-1977 Resident District Hospital Gerolzhofen and Carl von Heß-Hospital-Hammelburg, Germany. 1977-1978 Research Fellow of the DFG Sonderforschungsbereich 105, Univ. of Würzburg, Germany. 1978-1979 Resident at the Department of Surgery, Univ. of Würzburg, Germany. 1979-1984 Resident and Specialist training Department of Urology, Univ. of Würzburg, Germany. 1984 Board Certification in Urology. 1984-1986 Specialist, Department of Urology, Univ. of Würzburg, Germany. 1986 Oberarzt (Consultant) University of Würzburg, Germany. 1986 Docent, University of Würzburg, Germany. 1990 Full Professor of Urology, University of Würzburg, Germany. 1992-2018 Distinguished Professor and Chairman Department of Urology, Technische Universität Dresden, Germany

Clinical Evaluation. Director/Examiner Clinical Trials according AMG and MPG

Honorary Offices. 2009 President German Society of Urology. Since 2004 Member of the Exec. Board European Society of Urology

Awards. Various awards. Several International Memberships of Honor and a Doctorate honoris causa.

Publications. More than 300 Medline listed publications. 8/50 Books and book contributions

Qualification according Article 6 MEDDEV 2.7/1 revision 4

Research methodology (including clinical investigation design and biostatistics):

Director/Examiner Clinical Trials according AMG, Doctoral Degree, Habilitation and 300 Medline listed publications

Information management (e.g. scientific background; experience with relevant databases such as Embase and Medline):

1977-today: university researcher and later Distinguished Professor and Chairman, Department of Urology, Technische Universität Dresden, Germany; more than 300 original Medline listed publications requiring comprehensive use of relevant databases such as Embase and Medline.

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):

1976-today postgraduate training and experience in Medicine including 1992-today as Distinguished Professor and Chairman, Department of Urology, Technische Universität Dresden, 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):

Urologist, Distinguished Professor and Chairman, Department of Urology, Technische Universität Dresden, Germany

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:

1976 M.D. in Medicine, 1977 Dr.med., 1984 Specialist, 1986 Dr. med. habil., 1979-today professional experience as Urologist.

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

1979- today professional experience as Urologist.