

PMC - Dr. Paul Meng Consultant

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Certificate

Dr. Ctibor Dostal (CZ)

attended an internal course on

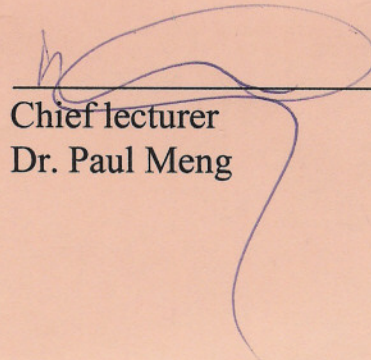
Good Clinical Practice and Study-related Topics

between the 17th and 18th of May 2003 in Vienna

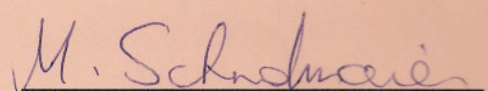
Topics covered:

Introduction to Clinical research	Indemnity, compensation and insurance
Phases of a clinical trial (I, II, III, IV)	Laboratory
Clinical trial design	Pre-study monitoring visits
History and development of GCP	Obtaining personal written informed consent
Good Clinical Practice – what is it?	Obtaining informed consents unable to give personal consent
Responsibilities of the investigator	Randomisation and stratification
Standard operating procedures	Blinding: Codes and code breaking
Organisation of clinical trials	Case Report Form (CRF) Completion
Preparation, approval and review of SOPs	Study drugs
Study team: definition and responsibilities	Monitoring visits
Study files and filing	Adverse Event and serious adverse event reporting
Local management requirements	Archiving
Case Report Form (CRF) review	Audits and inspections
Ethics Committee	

Vienna, 18th of May 2003



Chief lecturer
Dr. Paul Meng



Assistant lecturer
Martin Schmidmaier