



Vienna School of Clinical Research, Public Health and Medical Education is proud to announce that from  
**MAY TO JULY 2021 A TRAINING COURSE ON „ADVANCED DIPLOMA PROGRAM IN CLINICAL RESEARCH“ WAS HELD FOR THE – NATIONAL HEALTH RESEARCH AUTHORITY (NHRA) – IN ZAMBIA.**

*Professor Godfrey Biemba, Director/CEO of NHRA and his team gave us the opportunity to support their mission.*



**Prof. Godfrey Biemba, Director/CEO of NHRA**

“To promote, regulate, and coordinate ethical conduct of quality health research and facilitate translation of all research products into evidence-based policies and programs that improve the health of the people of Zambia and beyond”.

<https://www.nhra.org.zm/>

**VSCR-LECTURES FOR ADVANCED DIPLOMA PROGRAM IN CLINICAL RESEARCH WERE GIVEN BY:**

**Prof. Heinrich Klech (Austria)**

Introduction to Clinical Research/ Publication Master Class

**Dr. Ingrid Klingmann (Belgium)**

Ethical aspects in clinical trials/Introduction to Good Clinical Practice (GCP)/Clinical project management

**Prof. Alexander Hönel (Austria)**

Regulatory approvals/authorization of clinical trials/Inspections/audits of clinical trials

**Prof. Bernd Minnich (Austria)**

Biomedical Statistics/Advanced Biomedical Statistics

For more information go to [www.vscr.at](http://www.vscr.at)

## COURSE DESCRIPTION

Protection and safety of study participants is of utmost importance in all clinical research projects. Review of all clinical research projects by independent ethics committees is therefore required. In this course the participants will explore the ethical aspects of clinical research, study participant protection and the work and processes of ethics committees. Research in vulnerable populations, such as children and incapacitated adults as well as difficult ethical cases in today's clinical research environment will also be covered. This course is suitable for ethics committees' members, researchers and all other staff involved in clinical research.

### KEY TOPICS

- Ethical Principles in Clinical Research
- The Central Role of the Declaration of Helsinki
- Conflicts between Ethical Principles
- Case Studies 1 and 2: Difficult Ethical Decisions
- Informed Consent Process in Different Patient Populations
- Case Study: Informed Consent Review
- Ethics Committee Function, Concerns and Systems
- Misconduct and Fraud

### LEARNING OUTCOMES

At the end of the course the participants will (be)

- able to develop and understand the principles and basic considerations of ethics in clinical research
- understand the legal, administrative and organizational aspects associated with ethics in clinical research
- familiar with the informed consent process in the competent adult patient and in vulnerable populations
- appreciate the roles, responsibilities and concern of ethics committees as defined by current regulations and practice
- understand ethical aspects in global clinical research
- sensitized to detection of misconduct and fraud

### COURSE DIRECTOR



#### Univ.-Prof. Dr. Heinrich Klech, MD, PhD, FCCP, GFMD

Professor of Medicine, Medical University Vienna, Chief Executive Officer of Vienna School of Clinical Research (VSCR)

Prof. Heinrich Klech is an internal medicine specialist by training from the University of Vienna. He is author of more than 200 publications in the field of lung diseases and served on the editorial board of many renowned medical journals in the field of Pulmonology and Internal medicine. He held various visiting professorships such as Mayo Clinic, Rochester, - Mont Sinai Hospital, New York, University of Nebraska, Omaha and Firestone Chest Unit, Hamilton-Ontario. After a successful international academic career he changed to executive R&D/medical affairs management positions in the pharmaceutical industry. He held position for Central Eastern Europe, Central Asia, Middle East and Africa for Eli Lilly & Company, and led later Lilly's R&D and regulatory activities in a large part of Western Europe. For long years he was the director of Lilly's Area Medical Center Vienna which served great parts of Western Europe, CEE and MENA and was constituted by more than 250 medical and regulatory employees. In 2020 he received the title GLOBAL FELLOW IN MEDICINES DEVELOPMENT (GFMD) by the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP) and its IFAPP Academy in recognition of his significant contributions and achievements for the promotion of awareness and advancement of Pharmaceutical Medicine as a global discipline and profession. Heinrich Klech is founder and managing director of the VSCR, which was founded by him in 2000, an independent non-profit organization, specialized for post graduate education in clinical research, health outcome research and related sciences. The VSCR is partnering with more than 15 Universities in Europe, Africa and the US. The VSCR provides academically certified courses up to a Master degree. As a recognized center of excellence the VSCR so far has trained more than 7000 physicians and scientists, ethics committee members, public health care decision makers, Pharma medical staff, and other clinical research professionals, out of 90 countries.

## OPERATIONAL DIRECTOR

**Mag. Margarete Schreiner-Karner**

Operational Manager of Vienna School of Clinical Research (VSCR)

Margarete Schreiner-Karner graduated from the Vienna University of Economics and Business Administration specializing in marketing and social policy. She began her career as a biomedical analyst in a medical-diagnostic laboratory for clinical chemistry and hematology, before joining the pharmaceutical industry in 2002. As product and brand manager, she was responsible for product launches, especially in the indications of obesity, diabetes with Sanofi and oncology with Takeda, in close cooperation with market access and medicine. Mrs. Schreiner-Karner was able to gather additional expertise in the context of conducting phase III clinical trials in the field of diabetes at MedUni Vienna, University Department of Internal Medicine III, Division of Endocrinology and Metabolism. In 2018 Mrs. Schreiner-Karner joined the VSCR team as operational manager and member of the VSCR management board. Since 2018 Mrs. Schreiner-Karner is responsible for planning and execution of postgraduate education for Pharma, Med-tech industry and physicians on national and global basis (Europe, US, Middle East, Africa, Kazakhstan) in the field of Market Access and Clinical Trials.

## FACULTY

**Dr. Ingrid Klingmann, MD, PhD, FFPM, FBCPM, GFMD**

European Forum for Good Clinical Practice (EFGCP), PHARMAPLEX bvba

Dr. Klingmann is a physician, specialized in General Medicine, Clinical Pharmacology and Pharmaceutical Medicine with over 30 years of experience in different senior operational and managerial functions in pharmaceutical companies, CROs and academic sites, focusing on clinical trial management, ethical and regulatory aspects. Since January 2003 she has been running her own pharmaceutical development and site management support consulting company.

Dr. Klingmann is Chairman of the Board of the European Forum for Good Clinical Practice (EFGCP). On behalf of EFGCP she was and is involved in different FP7- and IMI-funded projects (ICREL, Patient Partner, PharmaTrain, EUPATI, Combacte-Magnet) and with her company in the FP7-funded paediatric LENA project and the IMI-project SPRINTT. Currently Dr. Klingmann is also President of PharmaTrain Federation.

Dr. Klingmann is Module Chair in the post-graduate Master Course in Regulatory Affairs at the University of Bonn, Germany, and is lecturer in the Diploma Course in Clinical Trial Practices and in the ECPM course at University of Basel and in the Pharmed course at Université Libre de Bruxelles, Belgium.

In 2020 she received the title GLOBAL FELLOW IN MEDICINES DEVELOPMENT (GFMD) by the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP) and its IFFAP Academy in recognition of her significant contributions and achievements for the promotion of awareness and advancement of Pharmaceutical Medicine as a global discipline and profession.

**Mag. Dr. Dr. Prof. h.c. Alexander Hönel**

Mag. Dr. Dr. Prof. h.c. Alexander Hönel holds a degree in law and a degree in politics/history from the University of Vienna, a degree in veterinary medicine, Vienna, a Master in Public Health (MBA), Master of Laws (LL.M.) in Medical Law and a MSc in Pharma Management. He is university lecturer at several universities in Austria, Germany and Italy, and established a seminar company for GxP in 2019. Mainly he is doing audits worldwide, special field of interest is clinical development. He spent 8 years in industry, as Medical Manager at Hoechst/Hoechst Marion Roussel and Schering in Austria, has built up the Austrian Federal Inspectorate and headed it from 2004 till 2014, is head of one of the major Ethics Committees in Austria, and acts as legal consultant in GxP. He is member of various international organizations, not only in GCP and GMP and Medical Devices, also in the board of the International Rescue Dog Association and active Member of the Red Cross. His work is presented in dozen publications, covering a broad field from Pharma, to law up to history. Dr. Alexander Hönel is board member of the NADA (Austrian Anti Doping Agency), was member of the management board of PIC/S (Pharmaceutical Inspection Cooperation Scheme), and EMA (European Medicines Agency) expert for GCP and Pharmacovigilance, member of EF-GCP, ClinOps-Circle Austria, and DGPharMed.

**Ao. Univ.-Prof. Mag. Dr. Bernd Minnich**

Ao. Univ.-Prof. Mag. Dr. Bernd Minnich, FRMS holds a degree in neurobiology and a degree in zoology and electron microscopy from the University of Salzburg. He is university professor at the Paris Lodron University of Salzburg / Dept. Biosciences (PLUS) and the Paracelsus Medical University (PMU) in Austria since 2003. His research interest focuses on vascular biology in animal experiments and applied human studies. Besides lecturing anatomy and physiology, he teaches biostatistics for more than 25 years in biology and medical classes. He is also coordinating courses on biostatistics and epidemiology for human medicine at the PMU.

After his habilitation in electron microscopy and vascular biology, he became head of several divisions at the University of Salzburg. Since 2008, he is member and reviewer of one of the major Ethics Committees in Austria and in 2020, he became vice head of the Ethics Committee of the federal state of Salzburg.

He is board member of the Austrian Society of Electron Microscopy (ASEM) and member of various international scientific organizations. In 2014, he was awarded the fellowship of the Royal Microscopy Society, Oxford, GB (FRMS).

His scientific work presented in more than 150 publications covers a broad field from developmental biology, vascular biology, NETosis research to clinical studies in cardio-vascular surgery.

Dr. Bernd Minnich was involved in various clinical studies in different fields of medical research by setting up study designs and performing biometry and statistical analysis.