School of Governance
Risk & Compliance
Steinbeis-Hochschule
Berlin

School of Criminal Investigation
& Forensic Science
Institut für Kriminalistik
Steinbeis-Hochschule Berlin

Lecturers – CRRA

Dr. Ferdinand Hundt

The Program Director of the certificate program in Clinical Research and Regulatory Affairs at the Health Department of the DUW Institut für Weiterbildung – DUW Institute for Professional Studies.

He is a licensed physician who worked as an anesthetist for the Klinikum der Johannes Gutenberg-Universität in Mainz from 1978 until 1988 when he joined the clinical research department of Janssen GmbH, Neuss. Since 1991 Ferdinand Hundt has held various positions in clinical research with Sanofi Deutsch-land, most recently holding the position of Director Special Projects in Berlin. Since 2013, he has been active as a consultant and senior advisor. From 1999 to 2010 he was head of the Committee Clinical Research/Quality Assurance of the Verband Forschender Arzneimittelhersteller e.V. (VfA) (Association of Research-Based Pharmaceutical Companies). He is a member of the Clinical Quality Assurance Group Germany (CQAG) and a Fellow of the Faculty of Pharmaceutical Medicine (FFPM)/Royal Colleges of Physicians (UK), as well as a member of the Fortbildungsausschuss der Landesärztekammer Berlin (Committee of Continous medical Education of the State Chamber of Physicians in Berlin). Furthermore, Ferdinand Hundt was responsible for the design and development of continuous professional training from 2010 - 2013 within the board of the Deutsche Gesellschaft für Pharmazeutische Medizin e.V. (DGPharMed).

Dr. Hans Rensland

Dr. Hans Rensland studied biology, biochemistry and biophysics at the Ruprecht-Karls-Universität Heidelberg and completed his doctorate in 1992 at the Max-Planck-Institut für Medizinische Forschung (MPI for Medical Research) in Heidelberg. From 1992-2012 he worked in big and small pharmaceutical companies with a broad range of medicinal products. His main focus is on regulatory affairs for drug development, dossier creation/ submission, scientific advice, and approval processes. In 2012 Hans Rensland started working as an independent consultant and founded his own consultancy company RACON - Regulatory Affairs Consulting in 2015.

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Dr. Doris Katharina Henn

Dr. Doris Katharina Henn has been working in the field of clinical research for more than 20 years. After completing her diploma and Ph. D. in molecular neurobiology, she worked as a Clinical Research Associate and project leader in a mid-size contract research organization before moving into the pharmaceutical industry. Here, she worked as a project leader for clinical studies and a clinical process manager. Doris Henn was head of the local quality management of the medical department and led the department of clinical research at AstraZeneca GmbH in Wedel, near Hamburg. After an international assignment in Warsaw, Poland, she currently holds the position of a Site Management & Monitoring Cluster Director, responsible for clinical trials in Germany, Austria, and Switzerland.

Dr. Andreas Palmer

Dr. Andreas Marc Palmer enrolled at the University of Cincinnati, USA and the Universität Stuttgart, where he concluded his studies in chemistry. He started his professional career as laboratory team leader in the area of drug discovery and development. During his ten-year tenure at ALTANA Pharma and Nycomed, he was responsible for the identification and optimization of active pharmaceutical ingredients for different therapeutic areas and the management of interdisciplinary project teams.

Dr. Palmer published the research findings in scientific journals and during his participation as invited speaker on international conferences. Additional studies in Clinical Research & Regulatory Affairs and his certification as Project Management Professional (PMP) complement his professional profile. In 2012, he joined the Global Project Management Team at STADA Arzneimittel AG.

In his current position as Senior Project Manager, Dr. Palmer is responsible for the realization of global development projects comprising all stages from project selection to launch of the generic product. Acting as interface to all technical departments, he is involved in the realization of clinical trials and the regulatory approval of the respective medicinal product.

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Dr. Hendrik Schmidt

Dr. Hendrik Schmidt studied Mathematics and Economics at the Universität Ulm (Germany) and Applied Mathematics at the University of Wisconsin-Milwaukee (USA). He obtained his Ph.D. (Dr.rer.nat.) from the Institute of Stochastics at the Universität Ulm and also holds a Diploma of Advanced Studies in Pharmaceutical Medicine from the Universität Basel (Switzerland).

Hendrik Schmidt started his professional career as a guest researcher at France Telecom Research and Development (Orange Labs) in Paris (France) before he joined Boehringer Ingelheim Pharma GmbH & Co. KG in 2007. Within the global Statistics Department he worked as trial statistician and was responsible for statistical input into the Medical Affairs organization incl. health economic and reimbursement issues across several therapeutic areas, notably respiratory diseases.

Since 2013, Hendrik Schmidt leads a team of senior-level statisticians with Boehringer Ingelheim with main focus on strategic-statistical support of late-stage development and post-marketing, and acts as Lead Statistician for a submission project.

Hendrik Schmidt was guest lecturer in Statistics at the Fachhochschule Bingen am Rhein (University of Applied Sciences) from 2010 to 2012 and is a tutor of biostatistics at DUW since 2013.

Dr. Thorsten Ruppert

Dr. Thorsten Ruppert is Senior Manager for Research, Development, and Innovation with Verband Forschender Arzneimittelhersteller e.V. – vfa (Association of Research-Based Pharmaceutical Companies). In 2000 he obtained a PhD in Biochemistry from the Freie Universität in Berlin for his work on catalytic RNA in the study group of Andres Jäschke. He then started to work with NOXXON Pharma AG as a scientist in the Research & Development Department. He switched to clinical research and later became Manager of Scientific Marketing, Business Development. In 2003, he joined vfa where he is – beside other areas – responsible for clinical trials and plays a central role in the clinical research field in Germany in coordination/cooperation with the 45 member companies of vfa. In this regard he also closely works together with the German regulatory authorities and ethics committees.

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Dr. Reinhard Nibler

Dr. Reinhard Nibler is a physician by training with board certifications in anesthesiology, emergency medicine, and medical quality management; he is also a TÜV Austria certified auditor. After clinical training, he started working in the pharmaceutical industry in 1998. After several positions in marketing, medical affairs, and clinical research, he finally took over the drug safety department of Essex Pharma in Munich.

In this position, he also acted as Stufenplanbeauftragter according to §63 Arzneimittelgesetz (German Drug Law) and was a member of the national pharmacovigilance working group of the Verband Forschender Arzneimittelhersteller e.V. (vfa). In 2004, he founded his own company Dr. Nibler & Partner, a consultancy and service provider for all aspects of pharmacovigilance.

He acts as a Qualified Person for Pharmacovigilance in the EU (EU-QPPV) for several companies, and is engaged in pharmacovigilance system audits and preparation for authority inspections.Reinhard Nibler has been president of the Mitteleuropäische Gesellschaft für Regulatory Affairs e.V. (MEGRA) and is a regular speaker at, and course leader of, pharmacovigilance-related training courses.

Dr. Birgit Ruhfus

Dr. Birgit Ruhfus studied biology at the University of Bochum. After obtaining a diploma in biological sciences she moved on to the Max-Planck-Institute for Molecular Physiology in Dortmund to work on her PhD thesis on a topic in cell physiology. In 1996 she obtained her doctoral degree in natural sciences (PhD). Joining Schering AG in 1997, she started as a clinical auditor conducting all types of audits of studies and systems. In 1999 she spent a year at Schering's U.S. affiliate to become acquainted with U.S. regulations while still working as compliance auditor in GCP and partially GMP as well. In August 2004 she moved on to Global Regulatory Affairs at Schering where she gained experience in submissions of clinical trial authorization applications, several types of variations, and extensions of clinical indications, mainly for centralized products.

In 2006, Birgit Ruhfus became head of Schering's Global Clinical Quality Assurance function. After the merger of Schering with Bayer she became Head of GCP Study Audit Management – Europe in 2007, responsible for overseeing the audit program for all Bayer Pharma studies in Europe. In 2013 Birgit Ruhfus was appointed Head Global GCP Study Audit Management. In this position she was globally responsible for the quality of all clinical studies conducted by Bayer. As of June 2015 she is Head of the Clinical Project Management for Ophthalmology, Hematology and Oncology marketed products. In this capacity Birgit Ruhfus is operationally responsible for executing Bayer's clinical trials globally in those indication areas.

Axel F. Wenzel BSc MSc PhD FTOPRA

Axel F. Wenzel BSc MSc PhD FTOPRA has extensive experience in drug development with a focus on regulatory affairs (DRA). After leading the medical microbiology diagnostics laboratory at the Universität des Saarlandes, medical faculty in Homburg, he acquired his pharmaceutical expertise in a range of positions in drug development at the Novartis Research Institute (formerly the Sandoz Research Institute) in Vienna, Austria and at Merck Sharp & Dohme, Germany, progressing from bench researcher to Head of Project Management and New Drug Development.

During the last 20 years, he has founded or cofounded and led several consultancies in the field of drug development (with a focus on DRA and pharmacovigilance), and he has been a founding and managing board member and the president (from 2006 to 2009) of The Organisation for Professionals in Regulatory Affairs (TOPRA), the largest such association in Europe. In addition, he was cofounder and, for more than five years, editor-in-chief of the journal TOPRA Regulatory Rapporteur, the largest EU-focused journal for DRA. He also is the First Vice President of the European Association of Pharma Biotechnology. Axel F. Wenzel teaches at the DUW Institut für Weiterbildung as well as at the Universität Duisburg-Essen. He is the author of many publications, ranging from topical contributions in regulatory and other scientific peer reviewed journals to contributions to scientific books and indiv. articles.

Friedhelm Leverkus

Friedhelm Leverkus holds a degree in Statistics which he obtained from the Universität Dortmund in 1988. He started his professional career at the Sozialforschungsstelle Dortmund (sfs). In 1991 he joined Pfizer, working as a biometrician, and was appointed Head of the Biometrics in 1995. In this capacity he was responsible for biometric support of clinical trials and noninterventional studies. Since 2010, Friedhelm Leverkus leads the Health Technology Assessment Group at Pfizer Germany, which is responsible for HTA and outcomes research and thus mainly for the development of AMNOG-Dossiers. For years, Mr. Leverkus is an active member of a working group within vfa – Verband der forschenden Pharmaunternehmen, Germany.

Dr. Gudrun Busch

Dr. Gudrun Busch is the owner of an independent consultancy for regulatory affairs. She held leading positions in Regulatory Affairs and Quality Management with drug/device companies in Germany and Switzerland for 17 years. She was responsible for the management of clinical studies and regulatory affairs for drugs, biologicals and medical devices. As a member of regulatory committees and trade associations she was involved in several working groups. Since 2007 she runs her own consultancy, focussed on regulatory strategy for medium and small sized companies in Europe. She is also active as an author

Gabriele Niedeggen

Gabriele Niedeggen is a paralegal by training and holds a postgraduate M.Sc. in Pharmaceutical Medicine (Universität Duisburg-Essen, Germany). She started her professional career in 1987 working for a Member of the German Parliament. In 2000, she joined the pharmaceutical Company Sanofi. Since then, she held several positions with responsibility for project coordination of medical studies within both the Clinical Study Unit and the Medical & Scientific Affairs Department. In 2013, she joined the Legal Department, being responsible for legal projects. In May 2017, she took over the function as Governance Officer within Sanofi, working closely together with Legal, Medical and Compliance and other relevant functions & departments ensuring healthcare compliance within the company - including Regulatory Affairs.