BULGARIAN ASSOCIATION FOR DRUG INFORMATION

Prof. Dr. rer. nat. Barbara Sickmüller is a pharmacist. She studied and obtained her doctorate at the Philipps University in Marburg - Germany (1967-1974).

From 1977 she worked as a scientific executive at the Association of the German Pharmaceutical Industry (BPI) and took over the section "Drug Safety" of BPI in 1979. 1984/1985 she had a sabbatical year in the USA with training into US drug legislation. From 1988 she was appointed as head of the department "Medical affairs" and from 1997 Director of the Medicines and Pharmacy Division of BPI. In 2000 she was appointed as Deputy Director General of BPI.

Since 1987 until 2011 she gave yearly lectures in the department of Pharmacy, University of Marburg, and was appointed honorary Professor of the University of Marburg/Lahn (Januar 2000). In addition, she gave lectures for the Master of Drug Regulatory Affairs at the University in Bonn. She had further teaching assignments at the Universities of Frankfurt and Heidelberg on Pharmacovigilance and clinical trials, and has published numerous publications and book contributions in these regulatory areas.

The German Ministry of Health appointed her as Member of the Advisory Committee on prescription of pharmaceutical products, the Commission on Medicines for Children and Adolescents (KAKJ) and member of the Board of Trustees of the Institute for Quality and Efficiency in Health Care (IQWiG) and a member of the Board of Trustees of the German Agency for Health Technology Assessment (HTA) at DIMDI.

She was member of several Working Groups of the Council for International Organizations of Medical Sciences (CIOMS) and the International Council for Harmonization of Marketing Authorization Requirements (ICH) in the areas of pharmacovigilance and clinical trials.

Since March 2012 she has retired and is now active as Senior Scientific Advisor for BPI. Furthermore,she gives lectures on Pharmacovigilance and clinical trials at the Universities in Bonn, Heidelberg and Marburg.

In July 2014 she was appointed President of the German Association for Regulatory Affairs (DGRA)in Bonn and in October 2014 as member of the university council of the University of Applied Sciences of Central Hesse (THM) in Gießen.

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Dr Brigitte Franke-Bray is an Independent Consultant with special expertise in Pharmaceutical Medicine. From September 2018 to March 2023 she was Treasurer and Board Member of IFAPP (ifapp.org) and still is a Board Member of PharmaTrain (pharmatrain.eu) and a member of the Advisory Board of ECPM (ecpm.unibas.ch). She has also been a board member of SGPM (sgpm.ch) for many years and a member of EUPATI (eupati.ch). She worked as a hospital physician in internal medicine, pneumology and allergology in Germany, then joined Ciba-Geigy in 1985 and afterwards Sandoz as a Medical Expert for respiratory diseases. In 1995 she joined Quintiles as Medical Director/Office Head Switzerland became Director DIA (diaglobal.org) Europe, Middle East, Africa, in 2005 and, additionally, the DIA's Global Training Officer. In 2013, she was a Clinical Reviewer at the Swiss Medicines Regulatory Authority Swissmedic in Marketing Authorisation before she became a globally acting Medical Director in the Respiratory Franchise in Novartis Basel, Switzerland, then started her consultancy in Pharmaceutical Medicine in 2018. Dr Franke-Bray has ample experience in Pharmaceutical Medicine education and training, also through the IMI (imi.europa.eu) projects PharmaTrain and EUPATI. She was a teacher and examiner at a diploma course at the University of Basel, Switzerland, and is a regular examiner at Basel University’s ECPM training course and also for the board-certified physicians’ specialisation in Pharmaceutical Medicine in Switzerland.

BULGARIAN ASSOCIATION FOR DRUG INFORMATION

CELEBRATING 10 YEARS ANNIVERSARY

Lena Gebert, M.D.R.A.

Lenas first career was in performing arts, beginning in the Soviet Union (USSR) where she studied classical piano at the Musikcollege. After moving to Germany she started a new career in natural sciences and regulatory affairs.

Today, Lena holds a degree as licensed pharmacist from Heinrich-Heine University Düsseldorf as well as a degree as Expert Pharmacist for Drug Information and Clinical Pharmacology. Lena is also a graduate from the Friedrich-Wilhelm-University Bonn and holds a Master degree in Drug Regulatory Affairs.

Lena started her industrial career in 2005 at Wyeth Pharma in Münster being responsible for all regulatory activities for products in the therapeutic areas vaccines and Neurology. At the beginning of 2006 she was appointed to Wyeth representative in the "Vaccines Working Group" of the German Federal Association of the Pharmaceutical Industry (BPI). In 2009 she joined Paul-Ehrlich-Institut (PEI), the Federal Agency of the German Federal Ministry of Health for Vaccines and Biomedicines where, as scientific officer and clinical assessor. At PEI, she was in charge for scientific evaluation of the clinical part of clinical trial applications, national and EMA scientific advices, and Marketing Authorisation Procedures with the main focus on Oncology. Lena also served as PEI representative in "Notice to Applicants Working Group" (NTA) at the EU-Commission (Brussels) and she has extensive experience in working in central regulatory groups at the European Medicinal Agency (London), including CHMP and SAWP as a national expert. After a ca 2- years-employment as a senior consultant for clinical development and regulatory affairs at NDA Regulatory Service GmbH she joined Oncology Research & Development Division of Merck Healthcare KGaA in Darmstadt as an associate Director and Global Regulatory Lead in 2017.

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CELEBRATING 10 YEARS ANNIVERSARY

Ekaterina Genova is a Doctor of Medicine, holding a degree from the Medical University of Sofia. She specialized in Ophthalmology and Neuro-ophthalmology. Dr Ekaterina Genova is a member of the Bulgarian Medical Association since 1999. After several successful years in the Military Medical Academy of Sofia, she joined the pharmaceutical industry, the German company Asta Medica in 1999.

Ekaterina Genova has a long and successful career in the healthcare and pharma industries through which she built an extensive network across the Bulgarian and Eurasian Markets. Since 2007 she has been responsible for the Business Development and Growth of Ecopharm - initiating cooperation with potential partners and building the product portfolio of the company. In 2014 Ekaterina took a year-long course at the Pharmaceutical Faculty in Sofia, which enhanced her knowledge in disciplines such as analysis, testing, pharmaceutical chemistry and technology which helped her to understand the end-to-end process of drug manufacturing. She was leading both the Business Development and Regulatory Departments of Ecopharm, and built the pharmacovigilance department of Ecopharm, including the whole pharmacovigilance system and processes.

Since 2014, Ekaterina has been a QPPV of Ecopharm. She is legally responsible for the safety of all medical products that the company sells and also acts as a single point of contact for EMA.

Throughout the years, Ekaterina has been both a participant and a lecturer at various courses and events related to the regulation of drugs and medical devices held by BADI, EMA, DIA and as well as other organizations. In 2016 she gained a Diploma in Health Management from the Medical University of Sofia.

In 2017, after years of experience both as a doctor and a lead in the pharmaceutical industry, Ekaterina decided to set up her own consultancy company. She has been advising start-ups and working on transformational projects for other companies, focusing innovation and technology in the healthcare sector. She has the ability to build the “big picture” and be seen as a trusted advisor.