DRUG REGULATORY AFFAIRS - update | Training Course | MODULE 1 | 07.10.2022

Pharmacovigilance - Regulatory Update, Part I | Online event Only

SPEAKERS

BULGARIAN ASSOCIATION FOR DRUG INFORMATION

CELEBRATING 10 YEARS ANNIVERSARY

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

Dr. rer. nat. Jan Uwe Schaefer

Dr. Jan Uwe Schaefer, PhD graduated from Kiel University in 1992 with a Master's degree in Chemistry. In 1995 he presented his PhD thesis with a topic of inorganic chemistry. His professional experience started in 1996 with the position of a scientific officer at BfArM, the Federal Institute for Drugs and Medical Devices in Germany. Since then he is working in the Pharmacovigilance Department, until 2013 in the unit Risk Assessment Procedures & Pharmacovigilance Inspections. In 2013 he changed to the unit Project Management. Since 2014 he is Deputy Head of the unit Project Management.

Renald Hennig, M.D.

Summary of Occupational Experience:

since Sep 2007 - SCRATCH Pharmacovigilance GmbH & Co. KG (previously GbR and GmbH), Butzbach, Germany
Senior Consultant & Managing Director

Nov 1998 – Aug 2007 - Novartis Vaccines (formerly Chiron Vaccines), Marburg, Executive Director Pharmacovigilance

May 1998 – Aug 2007 - Chiron Behring GmbH & Co. KG, Marburg
Head of Pharmacovigilance

Oct 1995 – Apr 1998 - Productmanager

Oct 1994 – Sep 1995 - Marion Merrell Dow, Berlin,
Training Manager

Mar 1993 – May 1994 - Arzneimittelwerk Dresden, Radebeul
Head of Training

July 1990 – Feb 1993 - Glaxo, Bad Oldesloe, Trainer

Jan 1989 – June 1990 - Radiology/Nuclear Med., Dr. Dinkel, Heilbronn Internship

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Konstantin Kachulev, MScPharm, MBA, PhD

Konstantin is expert in drug safety, pharmacovigilance, medical device vigilance, cosmetovigilance and clinical research. He has management experience in pharmaceutical production, medicines' and food supplements' trading. Business development experience. Konstantin possess professional organization's leadership with event and training courses management experience.

Currently he is Senior Project and Portfolio Pharmacovigilance Manager. He gained 16 years of experience in the pharmaceutical industry, 10 years of which are experience in pharmacovigilance in both clinical and post approval settings across all therapeutic areas emphasizing on Oncology, Infectious disease including COVID-19, Neurology; Paediatric studies; experience with Rare Diseases, Vaccines and Medical Devices. Konstantin is an experienced pharmacovigilance professional with a history of success in building and leading local and global PV teams that deliver on time and with quality no matter if clients are located in the same Geography or cross continental.

Over the course of his career, Konstantin has held positions in PPD, Excelya and LabCorp starting from Safety specialist, Business development officer, Senior Associate up to Pharmacovigilance Manager with Project and Portfolio responsibilities. Before joining PrimeVigilance, Konstantin has worked for LabCorp in the role of Manager and Portfolio SME for Pharmacovigilance and Drug Safety covering portfolio management activities, client communication responsibilities, project documentation's creation, people/managers management. Konstantin holds a master's degree in Pharmacy with additional three pharmaceutical specialties – Industrial pharmacy, Toxicology and toxicological analysis and Legal regulation in healthcare; Master's degree in Clinical trials management; and PhD in Social medicine and management of healthcare and pharmacy. He covered hundreds of courses in the field of drug regulation, pharmaceutical business, and healthcare. Konstantin is also a guest lecturer in pharmacovigilance in the master course of Clinical trials management held by Faculty on Public Health in Medical University – Sofia and the President of the Regional pharmaceutical association – Blagoevgrad.

Married with two lovely daughters.

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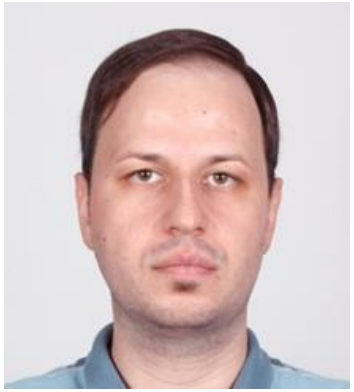

Valentin Kopanarov, MPharm

Valentin Kopanarov holds a Master of Science in Pharmacy from the Medical University in Sofia, Bulgaria. Building on a three-year foundation as a pharmacist, he has more than eight years of pharmacovigilance experience, both with clinical trials and with marketed products. His therapeutic expertise spans nervous system, digestive system, dermatology, hematology, infectious/parasitic diseases, oncology and rare diseases.

Valentin joined a leading global contract research organization in 2012 as a Drug Safety Specialist. Through a series of increased levels of responsibility including the roles of Senior Safety Specialist, Principal Safety Specialist, Manager Pharmacovigilance, Senior Manager Pharmacovigilance, Valentin assumed his current role of Associate Director Pharmacovigilance in Aug 2018.

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Margarita Strokova, MD has master's degree in Medicine from Medical University, Sofia and Master of Business Administration from New Bulgarian University, Sofia. Joined Pharma Industry in 1997 and has extensive experience in pharmaceutical marketing, scientific communication, Medical Governance and Pharmacovigilance (for products both under clinical trials and marketed). Worked for over 13 years as local person responsible for Pharmacovigilance in GSK Bulgaria and 3 years as Local Country Medical Head. Margarita has experience in safety operations (MI and PV) and from September 2021 is part of PharmaLex team.

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Maria Popova, MD, PhD

Dr. Maria Popova is head of “Pharmacovigilance and Clinical trials” Department in the Bulgarian Drug Agency.
Maria Popova is medical doctor graduated Medical Academy Sofia. She has specialty on pharmacology and theses: “Drug utilization and pharmacoeconomics of the national pattern of prescribing antibiotics”.
She was member of the first and second National Positive Medicine List’s Committee. Dr Popova has additional experience in the field advertising of medicines and is current vice chair of the Expert Council on Medicine’s Advertising. Representative of Bulgaria within the CHMP Pharmacovigilance Working Party since 2005. Representative of Bulgaria in the Pharmacovigilance Risk Assessment Committee (PRAC) since July 2012.

In July 2014 is appointed as chair of the new national Committee for Risk Assessment in Pharmacovigilance to the executive director of the Bulgarian Drug Agency. The last three years Dr Popova is assessors of PSURs when Bulgaria is appointed as Lead Member State in PSUSA procedures.

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Yordanka Ralinska, August Research

Yordanka Ralinska is a Pharmacovigilance manager at August Research since 2021. She has spent 10 years in the pharmaceutical industry starting her pharmacovigilance journey with PPD and going on to Sanofi as a Country Safety Head back-up. Previously, she worked for the Bulgarian Academy of Sciences. Yordanka has a Master Degree in Virology.

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Prof. Tatyana Benisheva - Dimitrova, DSc., President of BADI is a professor in the Faculty of Public Health at Medical University, Sofia. After receiving an EC-CADREAC scholarship she completed master's degree in Drug Regulatory Affairs (2004/2005) at the University of Bonn and later in 2010 a Master degree in "Public Health" at the Medical University of Sofia, Bulgaria.
She was a Director of the "Drug Policy" Department at the Ministry of Health (2000-2005) and has over 10 years of experience at the Bulgarian Drug Agency (BDA). As the first president of the National Council on Prices and Reimbursement of Medicinal Products 2013-2014 she started an EU-project-OPAC for establishing of electronic database of medicinal product.

As a managing director of consulting in Bulgaria Betaconsult Pharma Ltd. (2007-2013) she developed activities at the global regulatory database IDRAC of the Thompson Reuters (2006-2012). She was involved like an expert in the project of the European Commission - PLAC assignment medicinal product pricing in Serbia, in 2016. Prof. Benisheva is member of DIA and DGRA and Board member of the EAMEA, Advisory council at the DIA in Europe, since 2017. Her 25 years of experience in drug regulatory affairs (life cycle management and market access of medicinal product) is complemented by more than 100 publications in the regulatory science field of medicines.