BULGARIAN ASSOCIATION FOR DRUG INFORMATION

CELEBRATING 10 YEARS ANNIVERSARY

# DRUG REGULATORY AFFAIRS – UPDATE TRAINING COURSE |

IN 3 MODULES

# SPEAKERS

## MODULE 2 | PHARMACOVIGILANCE, PART II - REGULATORY UPDATE - FROM REGULATORY PRACTICE

NOVEMBER 06, 2020 | HOTEL FORUM, SOFIA, BULGARIA |
ONLINE VIA WEBEX PLATFORM

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**Dr. Vili Topalova, MD**

Currently a CEO and Medical Director at AV Consult Pharm Ltd.

Senior Manager Regulatory Affairs & Pharmacovigilance of Pharmalex Bulgaria, EU QPPV

Vili Topalova graduated the Medical University, Sofia as medical doctor. She has worked as a physician, as a neurologist at the Military Medical Academy for 22 years. Vili Topalova joined the pharmaceutical industry in 2003. Her first appointment was for the position medical representative of Inbiotech. Three years later she has started working in the BDA, first as senior expert in Department "Marketing Authorization of medicinal products“, and that as Head of the same Department. As an expert on Pharmacovigilance she has worked in PharmAdvice. In 2013 she started worked as Medical director of the Bulgarian office of Lindeq. She has experience to activities of pharmacovigilance shown below: Practical pharmacovigilance; Pharmacovigilance management; Establishing and maintaining PV systems; ;Audits and participating / preparation for inspections; Risk Management; Signal detection; Medical review; Validation of PV databases and data migration; Electronic reporting (certificate EudraVigilance); Project management MedDRA; PSMF; Medical Device Vigilance; Cosmetovigilance; SOPs.

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**Rumyana Sharenkova, Chem. Eng.,** graduated the University of Chemical Technology and Metallurgy in Sofia in 1987 with Master's degree in Chemical Engineering and major in Organic Synthesis. In 1995 she obtained also Master's degree in International Economic Relations at the University of National & World Economy in Sofia. Her professional experience started in the Chemical and Pharmaceutical Research Institute in Sofia in 1988 in the Department of Antibiotics. In 1991 she obtained Research Associate III$^{rd}$ degree in Antibiotics. Since 1995 she has been working in the pharmaceutical business, gaining regulatory experience at the companies Zentiva (1997-2005) as Regulatory Manager and Actavis Bulgaria as Regulatory Affairs Director (2006-2014). In September 2014 she joined the team of Chemax Pharma Ltd as Head of Regulatory Affairs Department.

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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). From November 2017 she is Country Medical Head and Person Responsible for Pharmacovigilance of GlaxoSmihKline Bulgaria.

Dr. Nedelina Kurtelova has graduated Medical University (Sofia), obtaining two master's degrees - Medicine ( 2014) and Public health and health management (2018).

She has been worked as a physian at the Emergency department in Military Medical Academy for 1 year ( 2014-2015). She has been a medical resident of respiratory medicine at SHATPD “St. Sofia “ since 2016.

Dr. Kurtelova has been part-time doctoral student at Clinical Center for Lung Diseases, Medical University of Sofia since 2019. The topic of her science work is “ Multiorgan ultrasound in diagnosisi of Pulmonary embolism “. She has been an assistant at Clinical Center for Lung Diseases, Medical University of Sofia since 2019.

Currently, she is teaching Respiratory diseases to both bulgarian students and foreigners.

Dr. Kurtelova speaks English, Russian and Spanish.

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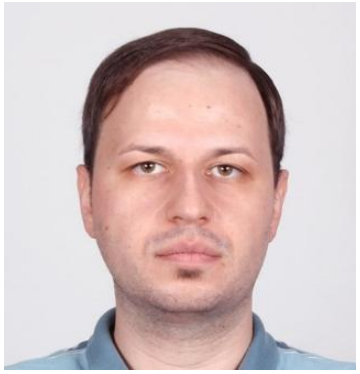

**Valentin Kopanarov, Mpharm**

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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**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.