DRUG REGULATORY AFFAIRS - update | Training Course | MODULE 3

December 02, 2022 | Online event only

SPEAKERS

BULGARIAN ASSOCIATION FOR DRUG INFORMATION

CELEBRATING 10 YEARS ANNIVERSARY

Ingrid Klingmann, MD, PhD, FFPM, FBCPM
PHARMAPLEX bv, EFGCP, PharmaTrain Federation, EUFEMED

Physician, specialized in General Medicine, Clinical Pharmacology and Pharmaceutical Medicine with over 30 years of experience in different senior medical, operational and managerial functions in pharmaceutical industry, CROs and clinical trial sites with focus on clinical trial design and management, ethical and regulatory aspects.
Since January 2003 she has 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). Her broad professional background as physician with experience in patient care, clinical development, site management, regulatory affairs, clinical research ethics, and patient engagement enables Dr Klingmann to bridge the gaps between the interests and skills of all different stakeholders in medicines development with the aim to develop new patient-relevant treatments more efficiently.
Dr Klingmann is currently also Secretary of EUFEMED, the European Federation of Exploratory Medicines and President of PharmaTrain Federation, the not-for-profit organisation focussing on global standardisation and improvement of post-graduate training in medicines development sciences. She also teaches on different clinical research and regulatory affairs topics in diploma and master courses at the University of Bonn, Germany, University of Basel, Switzerland, and the Université Libre de Bruxelles, Belgium.

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Mihai Rotaru is a Senior Manager Market Access at EFPIA (European Federation of Pharmaceutical Industries and Associations).

His main responsibilities revolve around the implementation of the EU HTA Regulation and preparing EFPIA members to navigate the future system of joint clinical assessment at EU level.
He is also coordinating broader oncology policy and supporting the EFPIA Oncology Platform, notably in its involvement in Europe's Beating Cancer Plan.
Mihai also has broader responsibilities in terms of biosimilar policy as well as supply chain issues (shortages, anti-counterfeiting).

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Rozalina Kulaksazova graduated from the Faculty of Pharmacy, Medical Academy in Sofia with a Master thesis. She obtained a specialty in Clinical Pharmacy as a post-graduate study.

In 1987 after a competition, Rozalina Kulaksazova joint the *Pharmaceutical Dosage Forms Section* at the Chemical Pharmaceutical Research Institute in Sofia as a research associate and worked in the field of parenteral dosage forms.

In 1999 Rozalina Kulaksazova joint the Bulgarian Drug Agency where currently she holds the position of Director of Drug Information and Non-interventional Studies Department. Her main responsibilities are focused on product information of centrally authorised medicinal products and related issues, and evaluation of post-authorisation studies. Currently Rozalina Kulaksazova is a member of the Committee for Advanced Therapies (CAT) at the European Medicines Agency. As a member of CAT she has been involved in the ATMPs classification procedure.

Rozalina Kulaksazova has been invited to deliver presentations in her field at different international regulatory and professional forums – in London, Berlin, Shanghai, etc.

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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 IIIrd 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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Dragomira Nikolaeva Nikolova, PhD

2012 – until now	Senior Assistant professor of medical genetics Medical University – Sofia, Medical Faculty, Zdrave, 2 Str http://medfac.mu-sofia.com/ ▪ Teaching medical genetics in Bulgarian and English to students of Medicine and Pharmacy, Students of Molecular Biology and Genetics Research and scientific activity
2016 – until now	Biologist to the Genetic laboratory, Clinic of Hematology, University Hospital „St.Ivan Rilski“, Sofia, Bulgaria
2012- 2009	Assistant Professor of medical genetics, Medical University – Sofia, Medical Faculty, Zdrave, 2 Str http://medfac.mu-sofia.com/
2010 -2009	Part-time lecturer of molecular medicine , New Bulgarian University, Department of Natural Sciences, https://nbu.bg/bg ▪ Lectures in biomedicine and genetics
2009-2005	Biologist Medical University – Sofia, Medical Faculty, Zdrave, 2 Str http://medfac.mu-sofia.com/ ▪ Diagnostic and research work

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Valeria Sarbinova graduated Master's degree from the University of Chemical Technology and Metallurgy, Sofia in chemical engineering in 2005.

Her professional experience started as a research and development manager at Ficosota Syntez global department. She started working for Novartis Consumer Health in 2014 as a regulatory and pharmacovigilance manager.

Throughout her professional experience, she had to upgrade her knowledge, skills and qualities in order to adapt to new companies and situations. She worked for Bulgarian companies Salvis pharma, Meditrial internationals and GS Consult Ltd. Valeria has more than 15 years of experience in the pharmaceutical and pharma-related industries field from various perspectives. Since 2021 is working as a consultant in the sphere of regulatory and pharmacovigilance as well as a consultant in good distribution practice for many companies: Vianex S.A, SIFI S.p.A, Galenica S.A., Agarta CM Ltd., Referance Ofta Ltd. Pharma Trade BG, D&Fisher Ltd, VeaMed and etc.

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Prof. Ilko Getov, PhD, MSc Pharm, MHM

Prof. Getov ss a professor at the Faculty of Pharmacy, Medical University Sofia. From July 2013 till Feb 2020 he was a President of the Bulgarian Pharmaceutical Union and from October 2017 to March 2019 chair of the HTA Commission at the Nacional Centre for Public Health and Analyses at the Ministry of Health. Prof Getov was First Vice President of Pharmaceutical Group of EU for 2016.

He has over twenty five years of professional experience as a pharmacist and manager of community and hospital pharmacy, pharmaceutical industry staff and consultant, and currently as an academic lecturer. He was a speaker in numerous scientific and practically oriented events for students, pharmacists, and other health professionals and industry; guest lecturer in Bulgarian and foreign universities, member of editorial boards and associate editor, expert of national and international bodies. From Oct 2020 he is member of CHMP at EMA with 3 years term.

Prof Getov has more than 160 scientific publications and 16 completed PhD students.

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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.