DRUG REGULATORY AFFAIRS UPDATE

TRAINING COURSE 2026 in 2 MODULES /Online

DRA Course - Online, 06 of November 2026 - Start 1 PM

MODULE 2 - SPEAKERS & MODERATORS

Maria Popova, MD, PhD 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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Associate Professor Dragomira Nikolaeva Nikolova, PhD, is a specialist in medical genetics, molecular biology, and laboratory immunology, with extensive academic, scientific, and diagnostic experience. Since September 2023, she has served as Associate Professor of Medical Genetics at the Faculty of Public Health, Medical University – Sofia, and since June 2023 as a Visiting Professor of Medical Genetics at the European University in Tbilisi. Her previous academic work includes many years of teaching and research at Medical University – Sofia, where she has taught medical genetics to students of Medicine, Pharmacy, Molecular Biology, and Genetics.
Her academic background includes a Bachelor's degree in Molecular Biology from Sofia University "St. Kliment Ohridski", a Master's degree in Genetics, and a PhD. She completed specialized training in cancer genetics at the Human Genome Center in Tokyo, as well as a Marie Curie International Postdoctoral Programme at Vita-Salute San Raffaele University in Milan, where she worked on the analysis of genetic data derived from exome sequencing. She also holds a specialization in Laboratory Immunology, with practical and theoretical experience in immune-system dysfunction.
Her scientific interests focus on gene therapy for common and rare genetic diseases, biomarkers and diagnostic methods, oncogenetics, gene-editing technologies, immunogenetics, and immunotherapy. She is a member of several Bulgarian and international scientific organizations, including the European Society of Human Genetics, European Association for Cancer Research, and European Society of Human Reproduction and Embryology. Her international academic experience has been supported by scholarships and awards for research and specialization in Japan, Italy, and at major European scientific conferences.

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 and later Cencora/Pharmalex company.

Rozalina Kulaksazova graduated from the Faculty of Pharmacy, Medical Academy in Sofia with a Master thesis. She obtained a speciality 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 dosageforms. 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. Her professional interests also include regulatory affairs in the fiels of medicinal products, use of real world data in decision making, advanced therapy medicinal products, etc.

Prof. Tatyana Benisheva is a president of Bulgarian Association for Drug Information (BADI) . She is a medical doctor and graduated from the Bulgarian Medical University – Sofia, Bulgaria. Since 2010 and she is a professor in the Faculty of Public Health at Medical University – Sofia, Bulgaria. After receiving an EC-CADREAC scholarship she completed Master' degree in Drug Regulatory Affairs (2004/2005) at the University of Bonn/Germany and later in 2010 a Master degree in "Public Health" at the Medical University - 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) and 3 years experience at the Health Committee and Sport at the Bulgarian Parliament (38 National Assembly in Bulgaria).

As the first president of the National Council on Prices and Reimbursement of Medicinal Products (national competent authority on prices, HTA and reimbursement) 2013-2014 she started an EU-project-OPAC for establishing of electronic database of medicines..

Managing director of pharma consulting in Bulgaria Betaconsult Pharma Ltd. (2007-2013) where 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 of medicinal product for pricing in Serbia, in 2016 and in EU project for pricing and reimbursement in Bulgaria. (2019-2021).

Her 25 years of experience in drug regulatory affairs (life cycle management and market access of medicinal products) is complemented by more than 100 publications in the regulatory science field of medicines.

At the moment she is full time professor at the Medical Universiry – Sofia Bulgaria in drug regulatory affairs in Masters – Pharmaceutical Management and Management of Clinical Trials.

Since 2023 she has been a member of the Central Ethic Committee for Clinical Trials at the Ministry of Health and is a member
of MedEthics EU.

Prof. Benisheva was a member of the EAMEA, Advisory council at the DIA in Europe. She is stil a member of DGRA and many national organisations.