



# BULGARIAN ASSOCIATION FOR DRUG INFORMATION

## **FOUNDATION SKILLS IN DRUG REGULATORY AFFAIRS MAY 18 - 19, 2023 | TRAINING COURSE**

Format: in person

Venue: "Prof. Dr. Alexander Chirkov" Hospital  
bul. "Pencho Slaveykov" 52, 1431 Sofia Center, Sofia, Bulgaria



**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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## **Daniela Cherneva, PhD**

Daniela Cherneva graduated from Sofia University “St. Kliment Ohridski” in 2008 with a Bachelor’s degree in Russian philology. In 2011 she graduated from New Bulgarian University in Sofia with Master’s degree in International Business and in June 2015 she obtained a Master’s degree in Public Health and Healthcare Management from the Faculty of Public Health of the Medical University in Sofia. In April 2021 Daniela obtained a PhD in the Faculty of Public Health, Medical University in Sofia with a dissertation on “Challenges in front of the reference pricing of generic medicines in Europe”. She has 13 years of experience in the Regulatory Affairs, currently in the position of Regulatory Affairs Manager in Medochemie Ltd. Bulgaria.

During her professional life she gained broad experience not only in Regulatory Affairs, but also in pricing and reimbursement, market access, pharmacovigilance, life-cycle product management, etc. Daniela has more than 16 publications and conference participations in the field of Regulatory Affairs and is a member of the Bulgarian Association for Drug Information (BADI) and the International Society for Pharmacoeconomic and Outcome Research (ISPOR).

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CELEBRATING 10 YEARS ANNIVERSARY



**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 joined 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 joined 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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### **Lyubina Todorova, MD, PhD in pharmacology**

Head of Department for Marketing Authorisation of Medicinal Products at Bulgarian Drug Agency since 2010.

Started working at BDA since 2001 and took several different positions including clinical assessor and Head of Department for Control of Blood transfusion system.

Since 2017 has been working as a member of Committee for Orphan Medicinal Products.



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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.



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**Elka Boncheva** – Graduated from Medical University, Sofia with a bachelor's degree in Medical Laboratory in 1995 and Master's degree in Pharmacy in 2001. Since March 2018 is a PhD student in Faculty of Public Health, Medical University - Sofia. She has 20 years of experience in Regulatory Affairs, Pharmacovigilance, Pricing, Reimbursement and HTA. Her professional experience started as a State Expert in the Drug Policy Department of the Ministry of Health, currently in pharmaceutical industry her main responsibilities are related to the initiation activities for strategic plans and opportunities to timely patient's access to innovative drug therapies. Member of BADI and ISPOR.



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## **Prof. Valentina Petkova, DSc, PhD, MPharm., MPH**

Prof. Valentina Petkova-Dimitrova, PhD is Vice-Rector for Science and Accreditation of MU-Sofia since 2016. She is Chair of the Council of medical Science. During the period 2012–2016 she was Deputy Dean for Academic Affairs for students studying in English at the Faculty of Pharmacy, MU-Sofia;

In 2015 she obtained the scientific degree of Doctor of Science after defending a dissertation on "Theoretical and applied aspects of the concept of" Pharmaceutical Care "in some specific groups of patients." In 2000 she successfully defended her PhD thesis on the topic "Study of the chronic patient's level of compliance" Master of Public Health and Health Management - PHC, MU-Sofia. She has acquired specialties in hospital pharmacy, clinical pharmacy, organization and economics of pharmaceutical production, organization and economics of pharmacy and distribution practice. Master in Marketing and Management at the Technical University, Sofia. Master of Pharmacy at the Faculty of Pharmacy, MU-Sofia.

She has more than 200 publication in Bulgarian and foreign scientific journals, 10 books and manuals and more than 75 participations in scientific meetings.

She has specialized in Germany (1998), Italy (1999, 2000) and the Netherlands (2006) in the sphere of Biostatistics, Epidemiology, Pharmacoepidemiology, Management and decision making in healthcare, and Pharmaceutical care.

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